IS4000 8mm Base Instruments CDR

September 29, 2011

ORION
FAST FOUR QUADRANT SURGERY

819005-03 Rev A

Agenda

- Core Team & Design Review Board - *Scott Harrington*
- Market & Product Requirements Overview - *Aaron Carrano*
- Instrument Design
  - Chassis Design - *Ed Donlon*
  - Inputs - *Don Alden*
  - Friction - *Ed Donlon*
- *Break! - 11:45am (Get Lunch)*
- Clinical Performance - *Maggie Nixon*
- Instrument Performance - *Hsien Hsin Liao*
  - Instrument Hooping performance
    - Comparison with IS3000
    - Modeling of contributors
  - Instrument grip force

Agenda - Continue

- Instrument Performance - continued
  - Safety and reliability - *Niels Smaby*
    - Simulated Life test and sine to death results
    - Wrist back-drive test results
  - Instrument behaviors - *Niels Smaby*
    - Engage trajectories, Grip cal, Cone limits, tool-data from RFID
- *Break! - 15 Minutes*
- **V&V Outline** - *Craig Tsuji*
- **Manufacturing Overview** - *Louis Spicciati*
- **Current RMA trends** - *Marc Bush (Jeff Rampe)*
- **Project Risks** - *Scott Harrington*
- **Schedule Overview** - *Scott Harrington*

Instruments Core Team

- Design Engineering:
  - Mechanical: Greg Dachs, Ed Donlon, Don Alden, Craig Tsuji, Katie Stoy, Andrew Crews
  - Electrical: Gerry Labonville / Brandon Garbus
  - Systems Analysis: Pushkar Hingwe
  - Software: Brent Tokarchuk
- Project Manager: Scott Harrington
- Product Manager: Aaron Carrano
- Clinical Development: Maggie Nixon
- Customer Service: Jamie Tobin
- Instrument Test: Dallan Schowe
- Manufacturing: Toni Conway
- Manufacturing Engineering: Louis Spicciati / Greg Richmond
- New Product Introduction / Mfg. Test: Garry Doran
- Supplier Development: Hung Pham
- [redacted]
- System Test: Steve Auer
- Technical Publications: John Gutierrez
- Purchasing: Chris D'Arienzo / Javed Khan
- Quality: Marc Bush

Instruments Design Review Board

- Clinical Affairs: ~~Victor Chen~~ N/A. No Clinical Trials. (Post-CDR Update)
- Clinical Development: Amy Kerdok
- Customer Service: Brett Robinson
- Mechanical Engineering: Bill Burbank
- Electrical Engineering: Rod Vance
- Manufacturing Engineering (ME): Mike Prindiville
- New Product Introduction: Bob Sundstrom
- NPI Purchasing: David Powers
- Materials: John Hill
- Product Management: Mike Hanuschik
- Product Quality: Krish Krishnanand
- [redacted]
- Software Engineering: Greg Toth
- Supplier Development: John Dovala
- Systems Analysis: David Robinson
- System Test: Joe Giallo/Lisa Heaton

IS4000 8mm Base Instruments CDR

Market and Product Requirements

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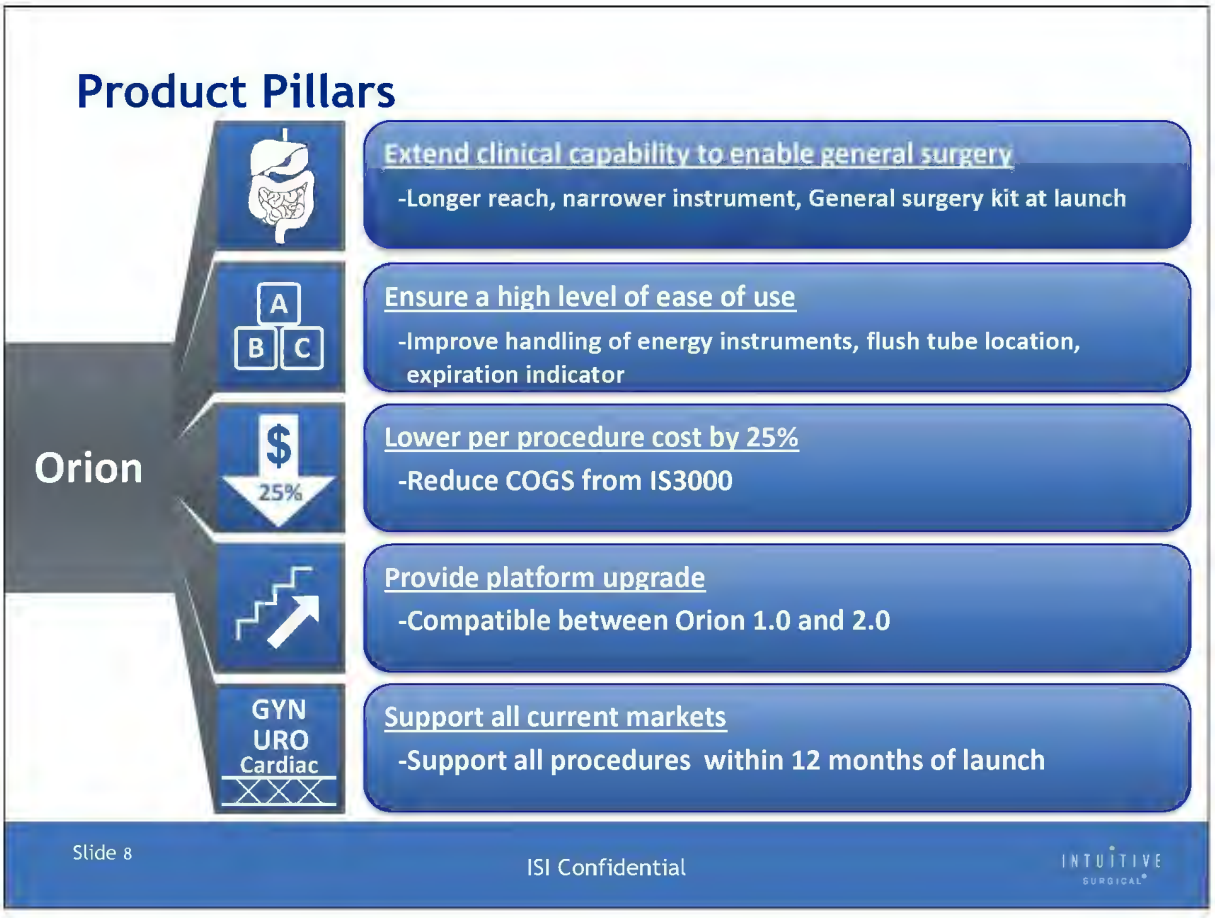
What's Covered?

Covered	Not Covered
8mm architecture	5mm architecture Advanced Instruments Harmonic ACE Tool Tracking Force Sensing PK Instrument *

* Working on the PK for Alpha 3.5. This project will have its own CDR.


Product Pillars
Orion
A
B
C
$
25%
GYN
URO
Cardiac
Extend clinical capability to enable general surgery
-Longer reach, narrower instrument, General surgery kit at launch
Ensure a high level of ease of use
-Improve handling of energy instruments, flush tube location, expiration indicator
Lower per procedure cost by 25%
-Reduce COGS from IS3000
Provide platform upgrade
-Compatible between Orion 1.0 and 2.0
Support all current markets
-Support all procedures within 12 months of launch
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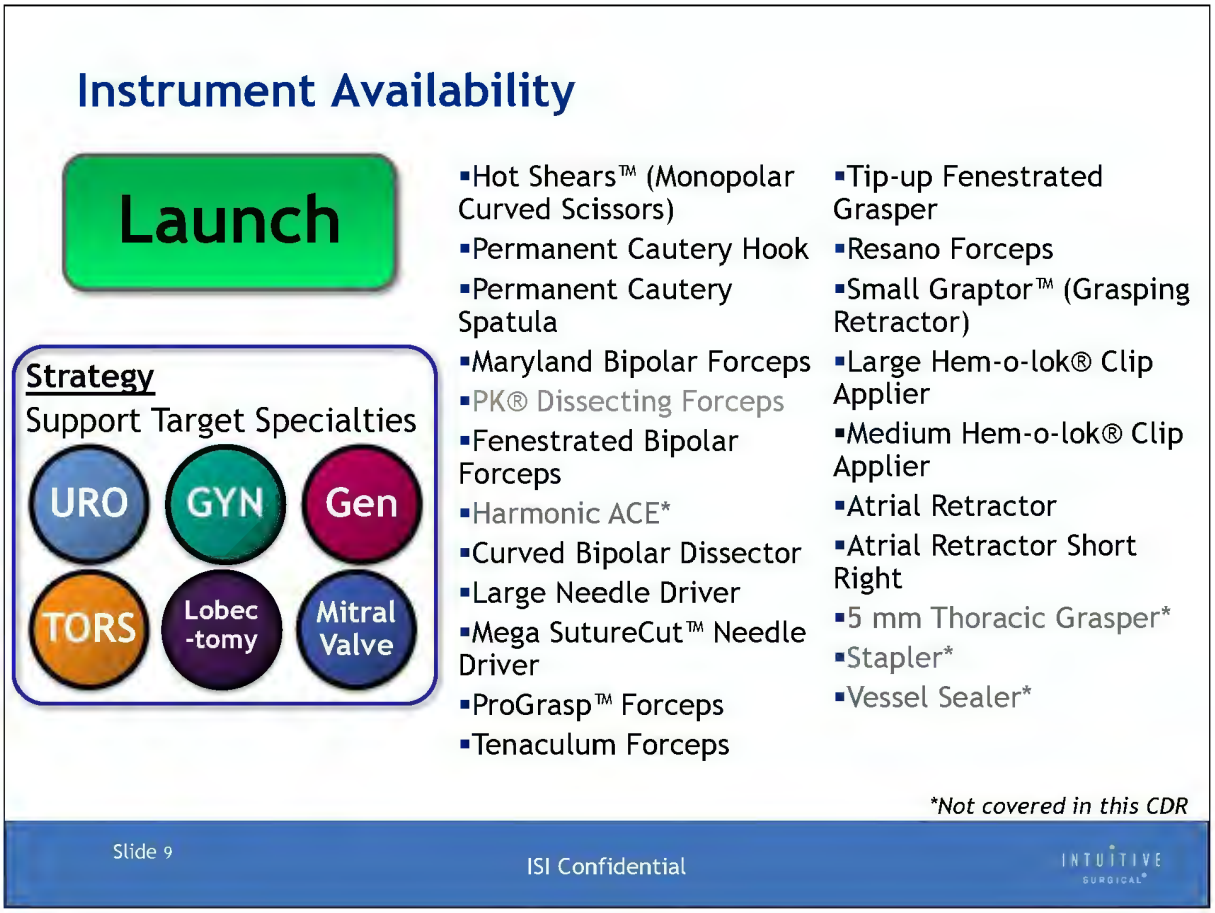


Exceptions: full 5mm set.

Instrument Availability

Phase II

Strategy
Complete sets for core

URO GYN

- Mega™ Needle Driver
- Large SutureCut™ Needle Driver
- Black Diamond Micro Forceps
- Cadiere Forceps
- Cobra Grasper
- Double Fenestrated Grasper
- Long Tip Forceps
- Graptor™ (Grasping Retractor)
- Round Tip Scissors

Instrument Availability

Phase III

Strategy
Complete set for cardiac

Mitral Valve

Revasc

- Micro Bipolar Forceps
- DeBakey Forceps
- Fine Tissue Forceps
- Pericardial Dissector
- Cardiac Probe Grasper
- Potts Scissors
- Small Clip Applier
- EndoWrist Stabilizer
- Snap-fit™ Instrument

Instrument Availability

Retire

- PreCise™ Bipolar Forceps
- Thoracic Grasper
- Curved Scissors
- Valve Hook
- Dual Blade Retractor
- EndoPass™ Delivery Instrument

Strategy
Discontinue low volume instruments

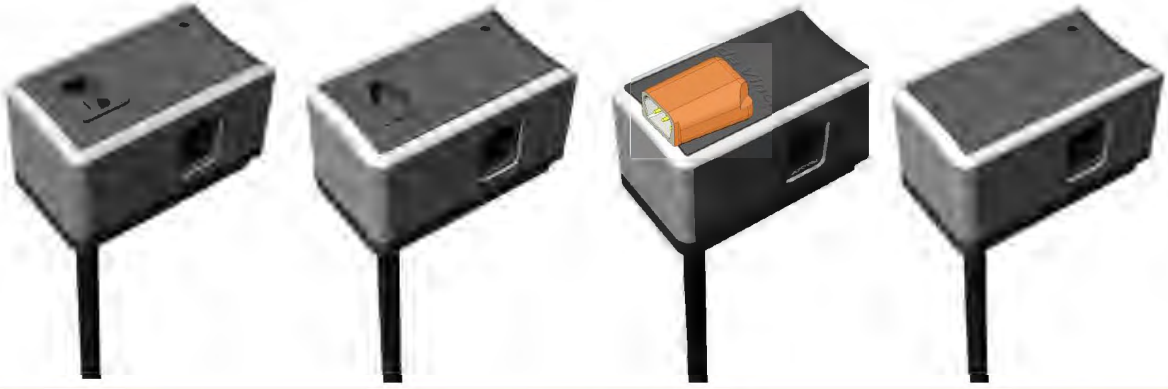
Instrument Availability - Summary*

Launch	22 instruments	Q2 2013
Phase II	10 instruments	Q3 2013
Phase III	9 instruments	Q2 2014
Retire	6 instruments	

Including advanced instruments, excluding 5mm instruments

Instrument Types

- Energy Instruments
  - Bipolar Energy
  - Monopolar Energy
  - PK Energy
- Non-energy Instruments



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Flush Ports

- Two ports necessary for cleaning
- Co-located with energy connector for Alpha 3
- Strong desire to move flush ports to rear of housing
  - Minimizes overall length when in the ultrasonic cleaner of instrument and simplifies user experience
- Engineering challenge
  - Additional bends in flush tubing reduces pressure

Opening Jaws

- IS3000 instruments have the ability to open jaws of the instrument by manually rotating protruding drive inputs
- IS4000 instrument drive inputs were modified to improve manual rotation

Emergency Release

- Allen key is used to back drive jaws
  - Same as IS3000

Labeling

- Instrument name visible from multiple orientations
  - On robot
  - Off robot
    - Central processing
    - Sterile back table
    - Sterilization tray

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End of Life Indicator*

- Utilize extra drive input
  - Rotate drive input to indicate instrument is expired
- Benefits
  - Improve OR efficiency
  - Prevent unnecessary reprocessing

Users attempt to use an expired instrument 1 in 8 procedures
(over 32,000 occurrences since 01/01/11)

**Identified as a "should" requirement in PRD*

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Instrument Design

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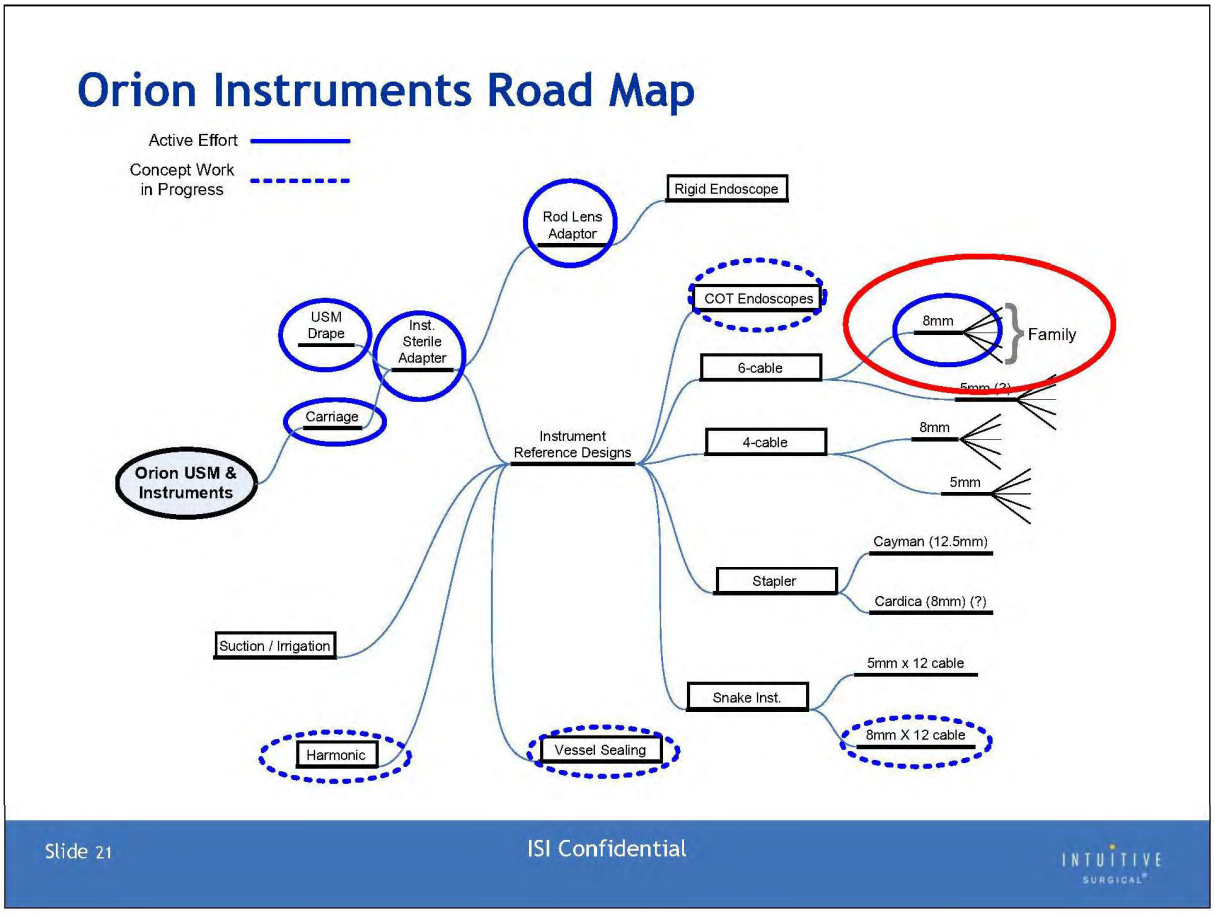
Orion Instruments Road Map
Active Effort
Concept Work in Progress
Orion USM & Instruments
Carriage
USM Drape
Inst. Sterile Adapter
Rod Lens Adaptor
Rigid Endoscope
Instrument Reference Designs
COT Endoscopes
6-cable
4-cable
Stapler
Snake Inst.
8mm
Family
8mm
5mm
Cayman (12.5mm)
Cardica (8mm) (?)
5mm x 12 cable
8mm X 12 cable
Suction / Irrigation
Harmonic
Vessel Sealing
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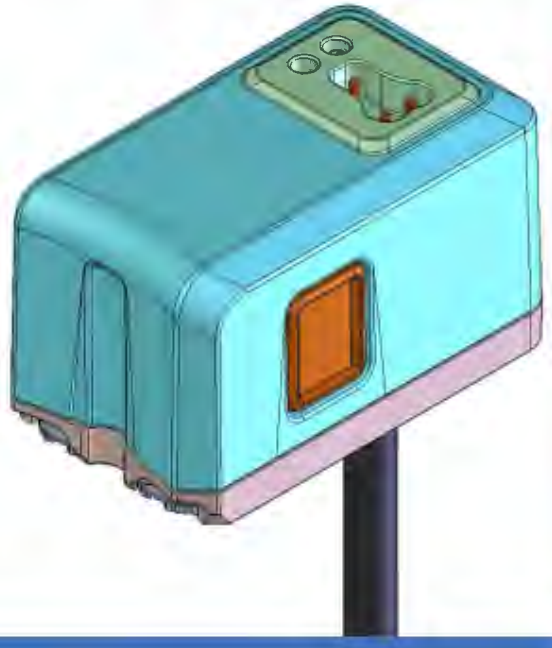
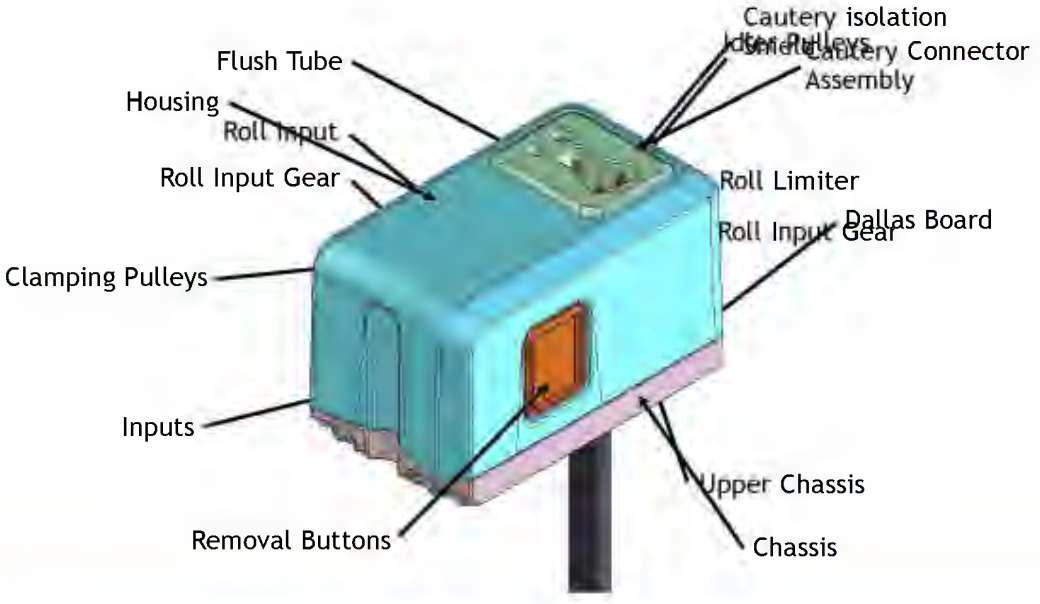
8mm 6-cable Architecture Overview

- Substantially the same architecture as presented at PDR
- Changes made to improve performance and manufacturability
- Heavy use of injection molded components
- Utilizes existing IS3000 Distal parts/assemblies



8mm 6-cable Architecture Backend

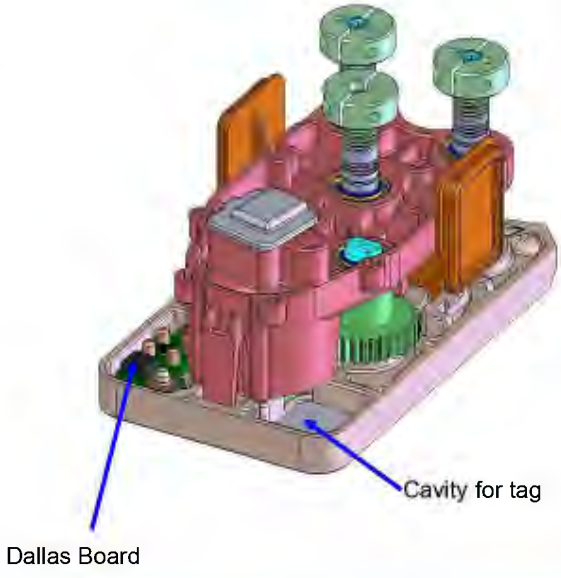


RFID & Dallas

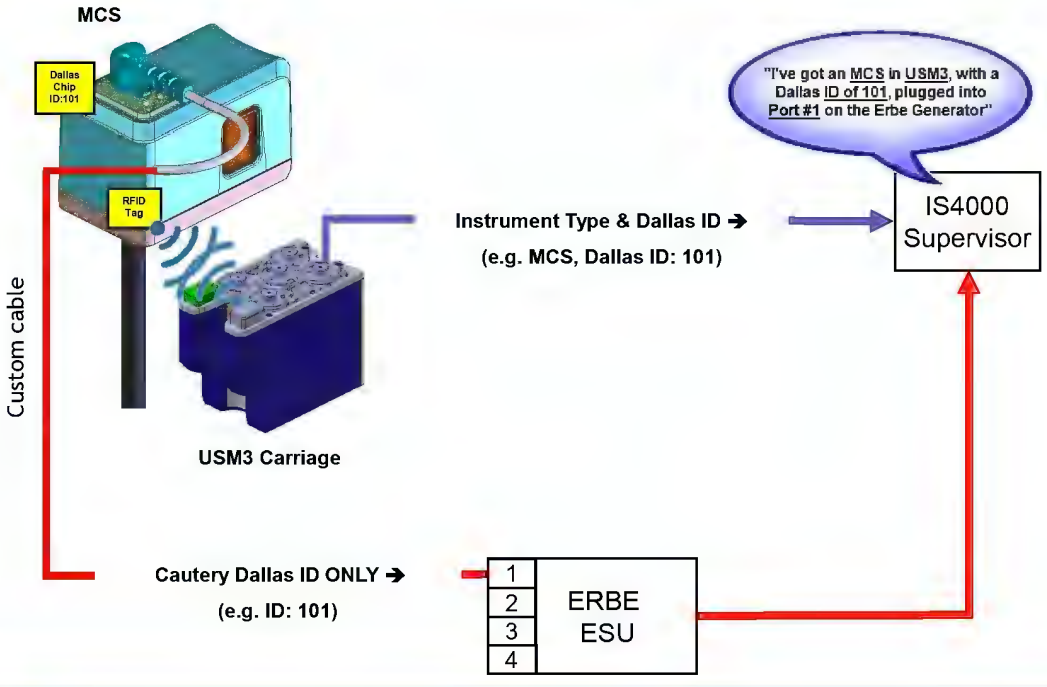
- Alpha3 Instruments will support both RFID and Dallas,
- Plan of record is to have RFID

- RFID Tag
  - 13mm Square
  - Likely held in with epoxy for A3
  - Will investigate snap or other retaining feature for A4/Beta

- Dallas Board
  - 4 spring loaded pins located on .180" square pattern
  - Held in place with (2) standard Tinnerman washers



Energy Instrument "Disambiguation"



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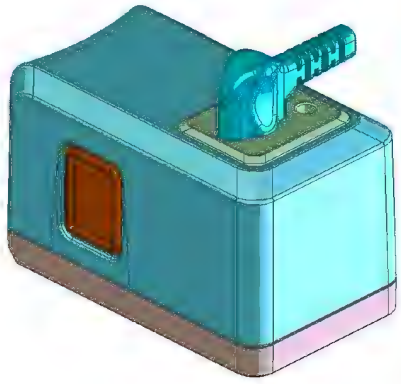
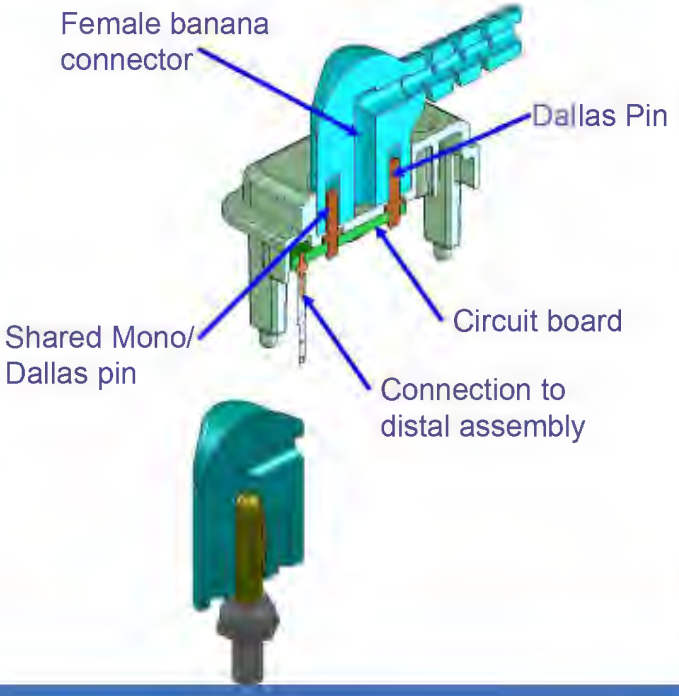
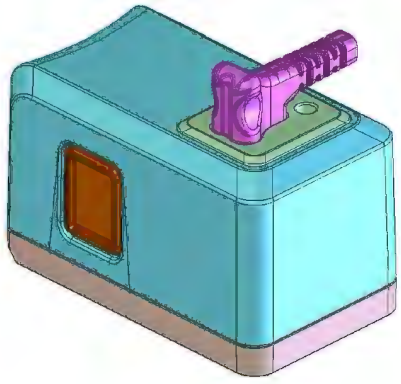
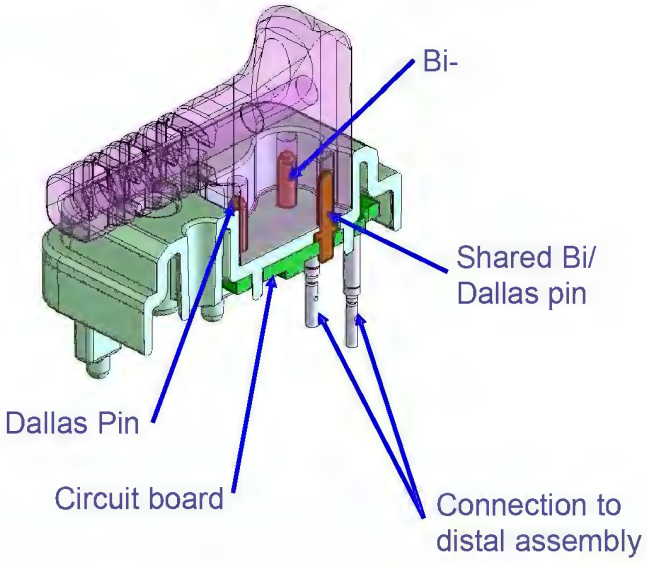
Integrated Energy (Monopolar) Instrument





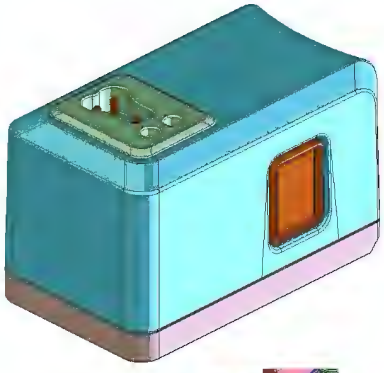
Integrated Energy (Bipolar) Instrument

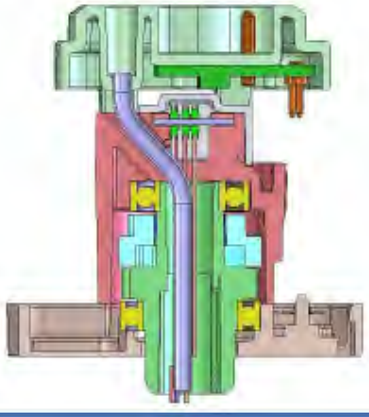


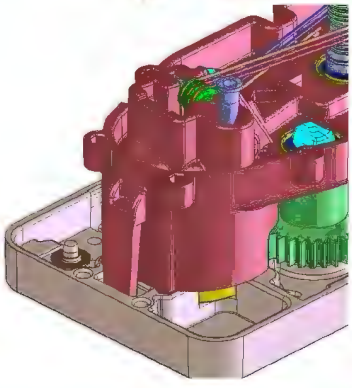


Cleaning and Sterilization

- Instrument is designed with standard autoclavable materials
- Instruments will be flushed like IS3000 instruments
- Cleaning verification will start with Alpha 3 Instruments







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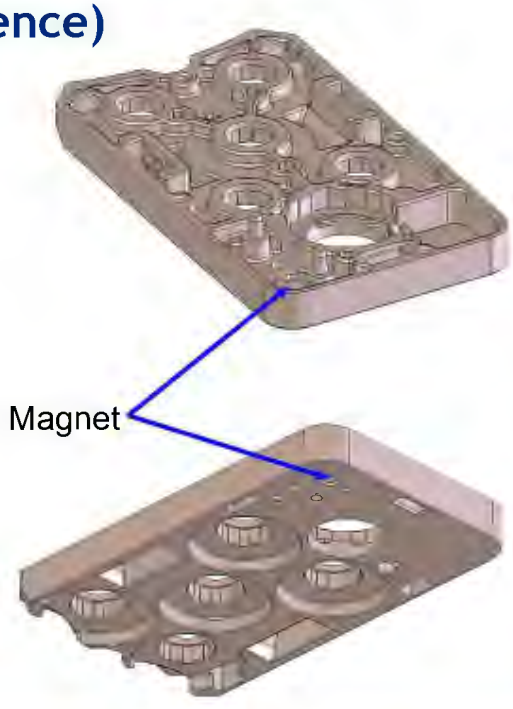
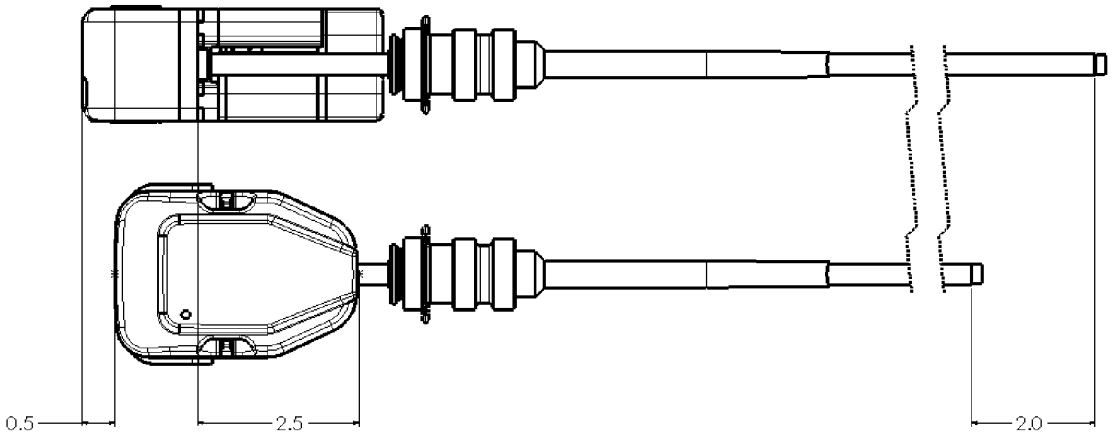
Magnet (Instrument Presence)

- Use to detect instrument removal
- Instrument will have a magnet similar to IS3000 instruments
- Material is the same, but slightly different geometry (thinner)
- Located under Dallas ID board



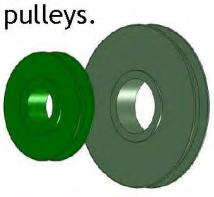
Instrument Length



Friction

- Only variable for friction is backend idler pulleys
  - Pulleys need to be as small as possible for packaging, but this adds friction
- Solution: Minimize shaft size and add low-friction coating to pulley and shaft.

- Pulley and shaft geometry not significantly changed from Alpha 2.
- Theoretical worst-case loading could yield 416 shaft, but no problems have been observed.
  - Higher-strength steel available if necessary.
- DLC coated shafts and TiNi pulleys
  - TiNi has same friction characteristics, increased life.
  - Easier to see cables on TiNi pulleys.



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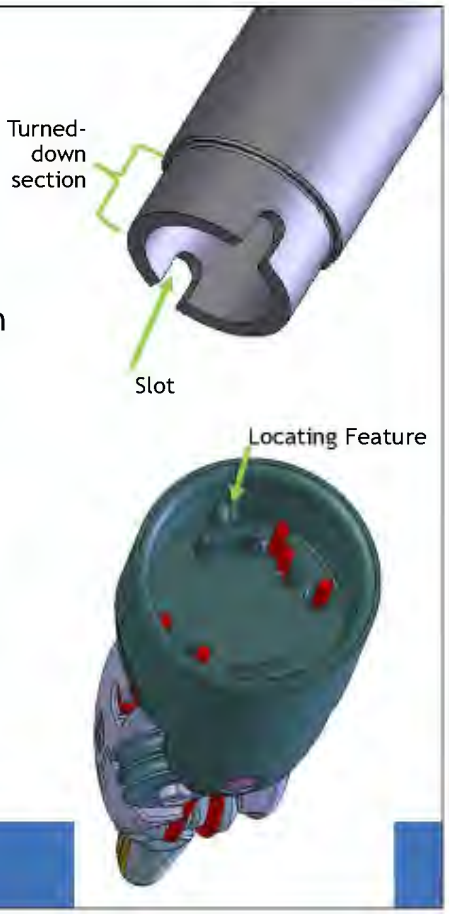
Update with photo of TiNi.

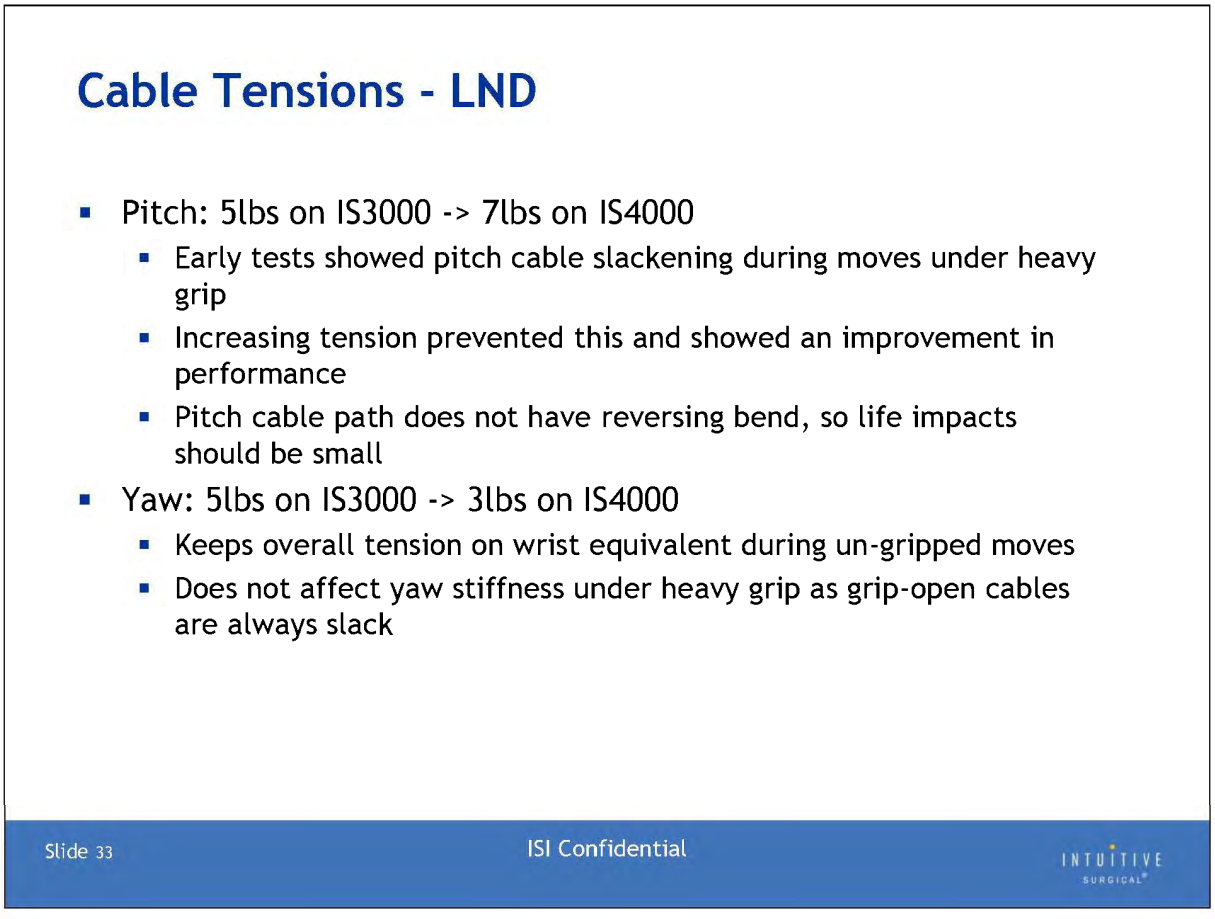
Seal Compliance

- Alpha 2 design showed relative motion of shaft and clevis during high grip.
  - "Sewing machine" effect in clinical eval
  - Pitch cables entirely slack under grip
- Alpha 2.5 opened up slot and reduced length of turned-down section to ensure no interference between shaft and clevis seal.
  - Uson test performance remained acceptable
  - Potential for rotation of clevis relative to shaft due to wide slots
- Alpha 3 design decreases length of turned-down section, increases depth of slot.
  - Slot width does not change relative to IS3000



Slide 32 ISI Confidential

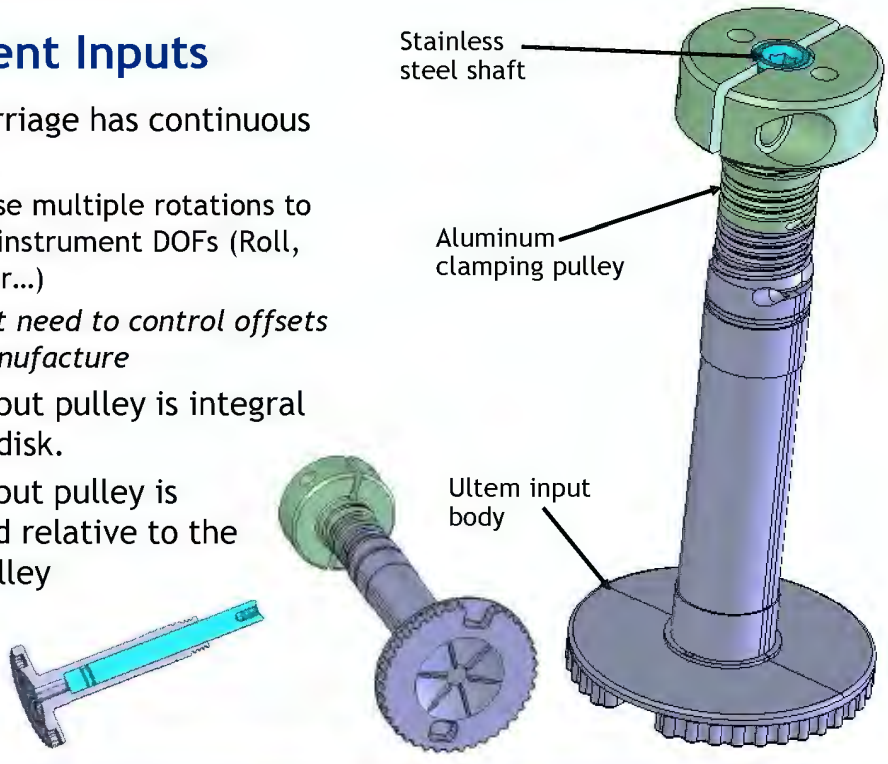
Update with photo of TiNi.



-Note that pitch performance has a large effect on hooping performance due to the long lever arm between the pitch axis and the tip of the instrument.
-Stiffness gets cut in half when one side of the cable loop goes slack. For pitch this is important as we want the stiffness to be high for optimal tracking. For grip it's less important because when grip is closed hard the grip-open cables are always going to be slack, unless the pretension is insane.

Instrument Inputs

- Orion carriage has continuous rotation.
  - Can use multiple rotations to drive instrument DOFs (Roll, stapler…)
  - *Do not need to control offsets at manufacture*
- Lower input pulley is integral to input disk.
- Upper input pulley is tensioned relative to the lower pulley

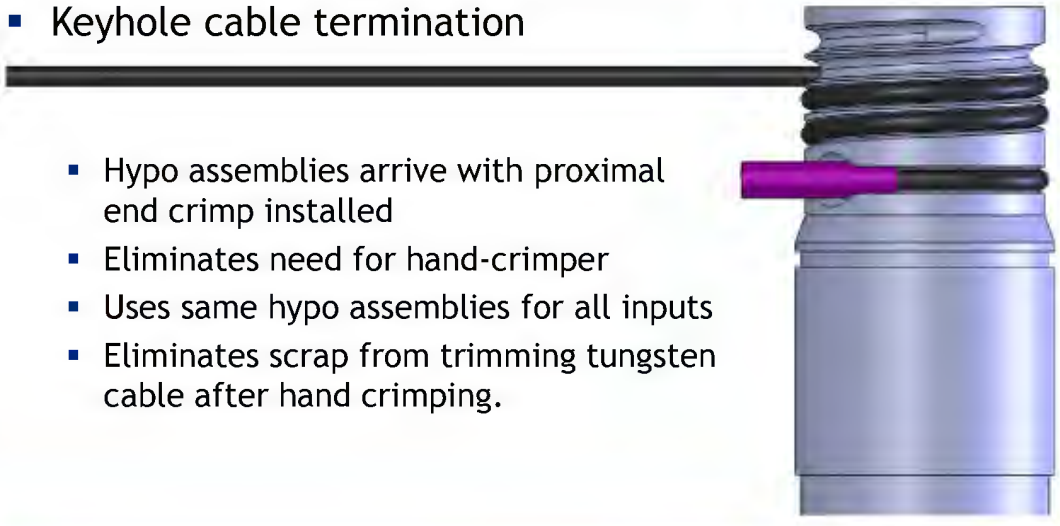


Slide 34 ISI Confidential INTUITIVE SURGICAL

Update! (Don Alden) No changes required. DA 26 Sep. Add section view

Input Pulleys

- Keyhole cable termination



  - Hypo assemblies arrive with proximal end crimp installed
  - Eliminates need for hand-crimper
  - Uses same hypo assemblies for all inputs
  - Eliminates scrap from trimming tungsten cable after hand crimping.

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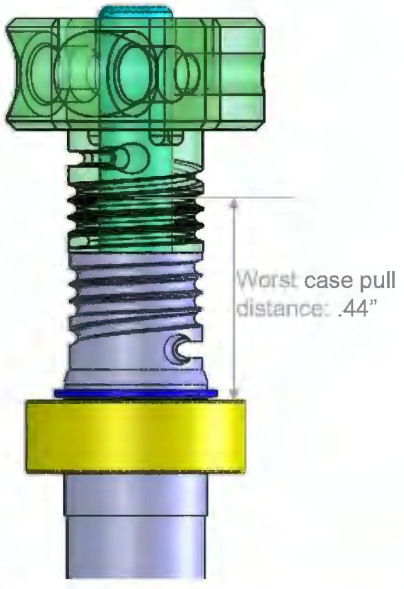
Update! (Don Alden) No changes required. DA 26 Sep. No changes from PDR. Does not waste Tungsten.

Clamping Pulleys and Shafts

- Bending Stresses:
  - Assume metal post takes all load
  - Larger (0.15” dia) shaft.
  - Assume 49lb load (break strength of cable)
  - Assume plastic adds no strength
  - Maximum von Mises Stress:
    - 68.5ksi → 17-4 PH Stainless Steel (replaces Aluminum)
    - 17-4 PH (H-1150) yield → 126ksi



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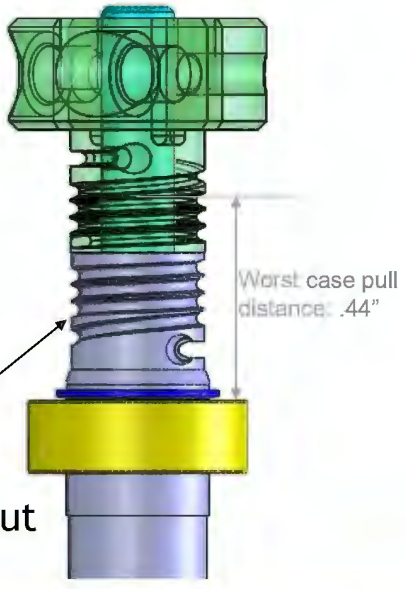
Update! (Don Alden)

Clamping Pulleys and Shafts

- Stiffness:
  - Resolve bending and twisting beam into cable pull
  - Assume stainless steel shaft (0.15" OD)
- 49 Lb causes cable deflection of .0035" if routed to top pulley
- Significantly less (.0016") if routed to lower



Grip close cable always goes to lower input

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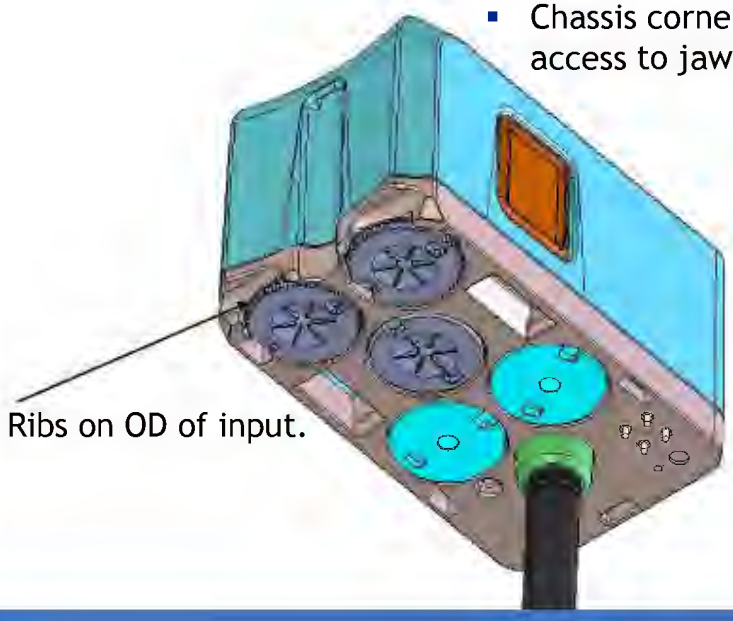
Update! (Don Alden)

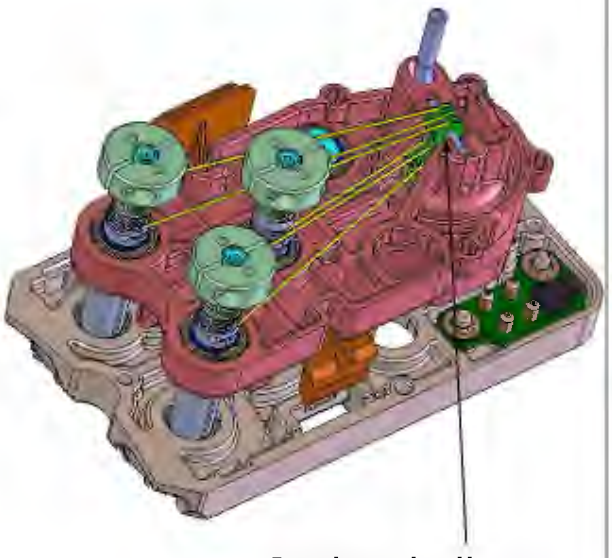
Jaw Cleaning

- Ribs added to jaw inputs to allow opening of jaws for safe cleaning.
- Chassis corners relieved to allow access to jaw inputs.



Instrument Cabling

- Routing adds 1.1” (2.75” total) to tungsten length
  - Compensated by using stiffer cable and using solid rod in place of hypo tube.
  - Reliable manufacturing process for rods has not yet been found.
- Fleet angles for jaw closing improve slightly from 3.7° to approximately 3.0 °.



Backend idlers

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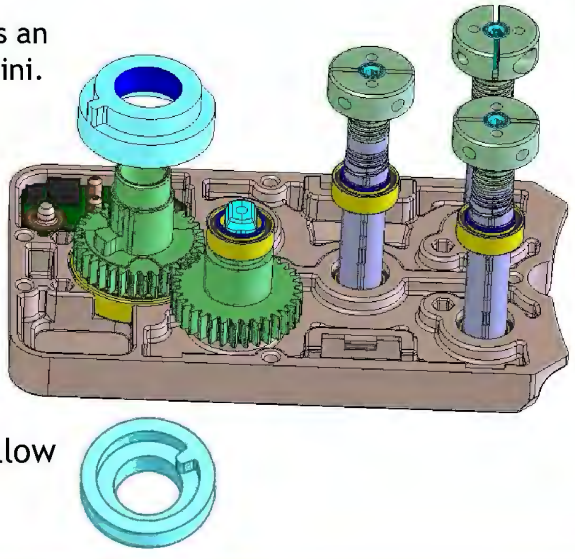
Update! (Ed Donlon and Katie Stoy) Rods are risky.

Instrument Roll

- Increased RoM
  - Elimination of twist axis allows reduced wrap of rods.
  - Roll ROM of 640° represents an increase over 520° for Gemini.
  - Reducing roll ROM from 640 ° will improve device life and reduce friction at extreme roll.
- Two-stage hard stop
- Direct drive, 1:1 gearing
  - Simplifies manufacture
  - Decreases part count
- Roll gear alignment marks allow fixed roll offset.



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No change but update image Show 640 deg. Tornado? Eliminates burden on roll axis

IS4000 8mm Base Instruments CDR

Clinical Performance

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Alpha2.5 Clinical Performance Testing

Performance tests -

- Instrument Hooping - how much the does the tip deviate when rolling around a fixed point at the tip
- Instrument Power grip - how does the instrument track to bumper position and grasp needles/tissue
- Master Tracking - how well does the instrument track to master inputs (sloppiness)
- Precision suturing - small needles, precise placement and gentle suture interaction
- 'Big bite' suturing - Needle purchase and following with tissue loads, firm suture pulling

Alpha2.5 Testing results

Performance Variable		Alpha2 results (March)		Alpha 2.5 results (September)
Instrument Hooping (LND)	2.5	Straight: 4 – 7mm diameter Bent: n/a	4 3.5	Straight: 1 – 2mm Bent: 4 – 5mm
Instrument power Grip	3	Grip Cal was off Trouble maintaining needle position in jaw		When grip cal working, power grip was equivalent to IS3000
Master tracking (inner axes only)	-		4 3.5	Yaw and pitch Grip (due to delay in grip tracking)
Fine Suturing	3	Some difficulty with tight control of needle tip.	4	Comparable time and stitch precision.
'Big bite' suturing		-	4	Needle grip and control was as expected Easily able to follow curve of the needle even with tissue load

1	2	3	4	5
unacceptable	worse	nearly acceptable	equal to IS3000	better than IS3000

Key Clinical Risks

Category	Detailed Hazard Identification & Rationale	System Behavior & Mitigation	Applicable Functional Area(s)
Imprecise Manipulator motion	Slack and/or friction in instrument (i.e. EndoWrist, snake wrist, single site, etc.) control could result in imprecise motion of instrument wrist causing tissue injury and/or inability to execute necessary surgical tasks.	Instrument movements are uniform (smooth and consistent) over their range of motion. Any backlash, hysteresis, friction, hooping, etc. shall be negligible. Life testing shall be performed to ensure intuitive motion is preserved over life of instrument.	I,M,A
Uncontrolled tip motion	Unintended system executed retraction of the insertion axis of the USM (i.e. due to a supposed instrument removal) could cause tissue injury if the instrument is still present.	System shall redundantly sense presence of instrument to a USM. Retraction of insertion axis for instrument removal only occurs after deliberate, user initiated event (i.e. both instrument release tabs are pressed).	I,M,A,S,E
Non-intuitive	An instrument may break, so that some instrument axes are unable to move as directed by the surgeon. This can cause overall instrument motion to be in an unexpected direction resulting in surgeon confusion and tissue injury.	Instruments shall be designed to withstand typical clinical use and reasonably expected abuse situations throughout the intended life of the instrument. Surgeons should be trained in recognizing the symptoms of unintuitive motion and what can cause it.	I,U

Key Clinical Risks (con't.)

Detailed Hazard Identification & Rationale	System Behavior & Mitigation	Applicable Functional Area(s)	Detailed Hazard Identification & Rationale
Loss of functionality	Instrument tip (including grips) does not stop or does not stop in a timely manner under a fault condition resulting in tissue injury.	The USM shall stop as soon as possible in accordance to the detection of a system fault. Regardless of USM position or action prior to the fault, the instrument tip shall coast to stop with little or no trauma to any tissue it contacts thus comparable to or less harmful that a dropped laparoscopic instrument. If gripping tissue, a system fault does not release the instrument grips.	M,A,S,E,U
Inability to access patient in emergency conversion	An Instrument gripping /clamping/suctioning or otherwise attached to tissue during a system fault could cause patient injury when it is removed.	The system shall provide a mechanism for quickly (~20 sec) releasing the instrument tips from tissue (i.e. grips, suction, clamping, etc.) during system faults or power losses, so that (a) the instrument releases the tissue, and (b) the sterile adapter releases the instrument.	I,U
Failure of patient contact components	Broken instruments and accessories may generate parts that are difficult to remove, and could cause injury if sharp or become lost in patient anatomy. Potential to result in conversion to open procedure for removal.	Instrument design shall be robust enough for typical clinical use and prevent particles falling into the patient. The User Manual contains appropriate warnings and instructions for safe handling, inspection, set-up & operation.	I,U

IS4000 8mm Base Instruments CDR

Instrument Performance

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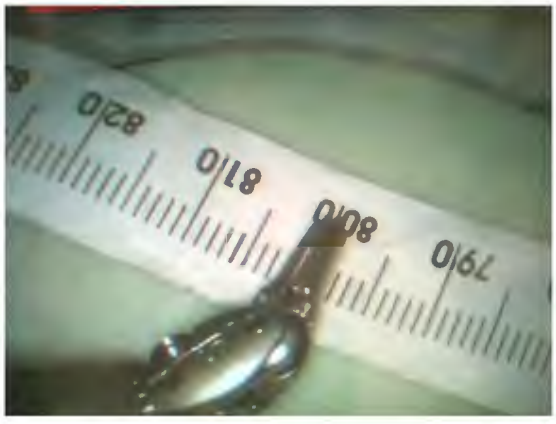
Agenda

- Performance
  - Instrument Hooping performance
    - Comparison with IS3000
    - Modeling of contributors
  - Instrument grip force
  - Instrument tip vibrations
    - Impact of torque ripple
- Safety and reliability
  - Post Fault behavior of instrument tip (HFHF)
  - Simulated Life test and sine to death results
  - Wrist back-drive test results
- Instrument behaviors
  - Engage trajectories, Grip cal, Cone limits, tool-data from RFID

INTUITIVE SURGICAL

Hooping (video from clinical lab)



- 45 deg. Pitch, 45 deg. Yaw

- 45 deg. Pitch

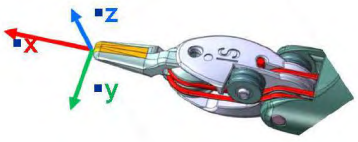
INTUITIVE SURGICAL

Hooping

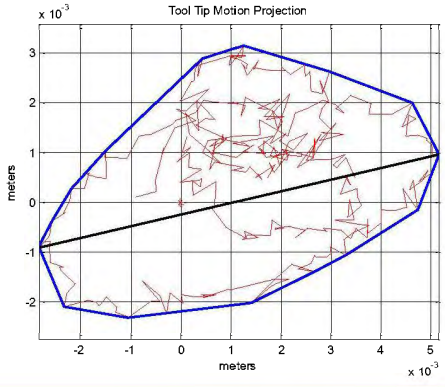
- Definition…
- Tip Motion is measured by a magnetic tracker.
  - Sensor motion is post-processed to get tool tip motion.

mention clinical hooping

Hooping Metric

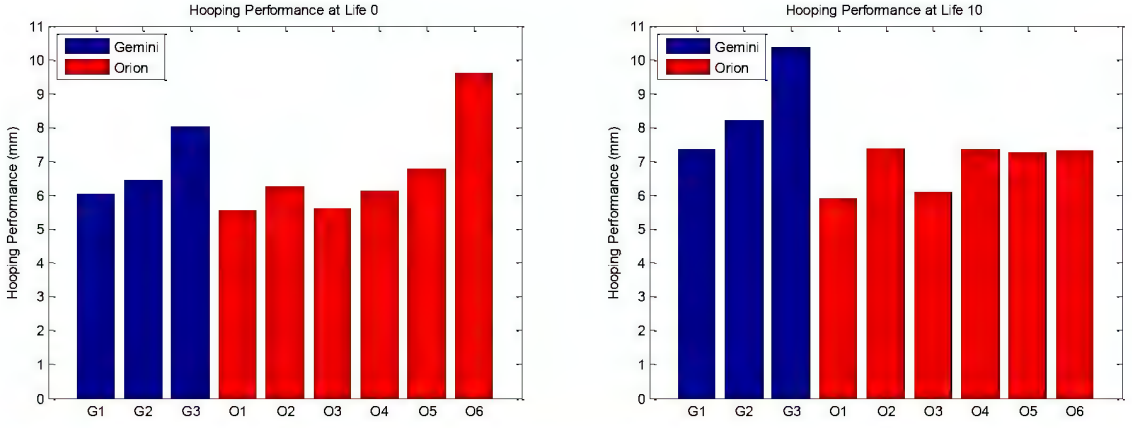


- Hooping Metric:
  - First project the tip motion onto a plane normal to the initial orientation (wrist pitch at 45 deg.), i.e., plane y-z.
  - Next find the convex hull housing the projected tip motion.
  - The maximum interior distance of convex hull is the metric.



Orion LNDs vs. IS3000 LNDs

- Orion LNDs have similar hooping performance compared to IS3K LNDs.
- Clinical engineers concur during instrument evaluation.
  - However, they usually report 2~2.5 mm LESS error than sensor measurement

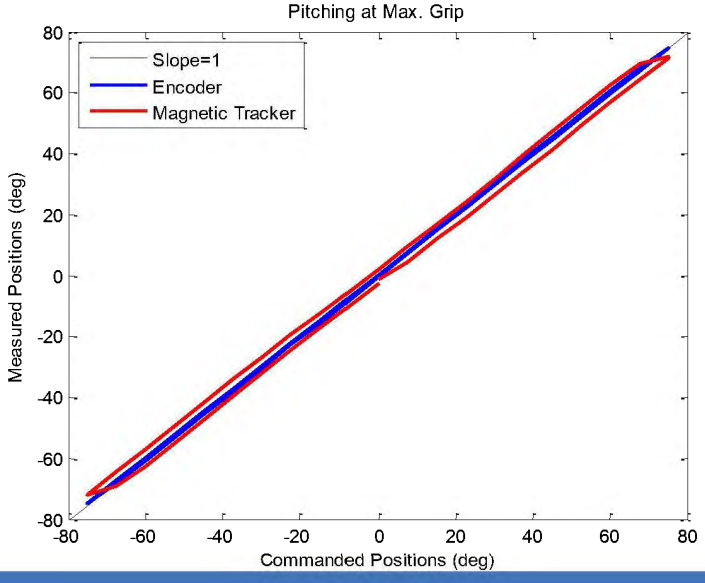


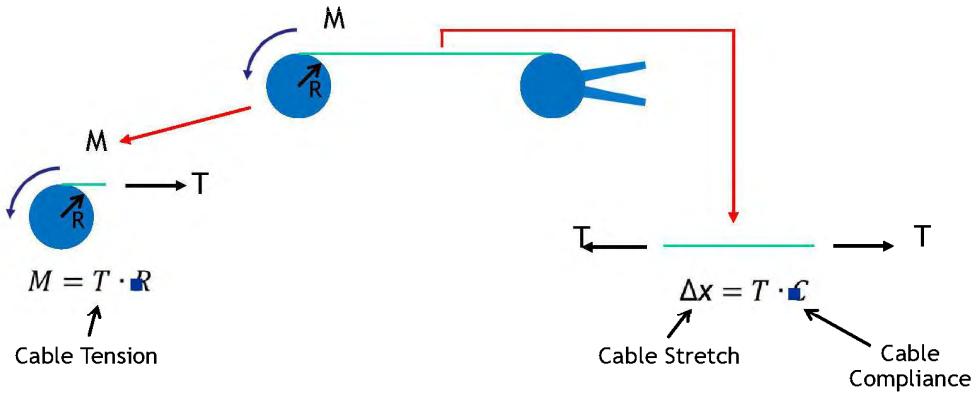
clinical engineers confirm this with lab sessions.

Source of Hooping Errors

- Want to understand the relative contributions of the following:
  - Measurement Error
    - Uncertainty in magnetic tracker mount position and noise
  - Servo Error
    - Difference between commanded and measured joint positions
  - Carriage and Sterile Adaptor Backlash
    - In a range of 2.5~4.5 degrees (Carriage 1.5~2 deg., Sterile adaptor 1~2.5 deg.)
    - Alpha3 likely has less backlash because ball bearings in the planetary gearbox
    - Actual disc position lags encoder by half backlash
  - Joint Offset
    - Tool "zero" positions not actually zero
    - Wrist pitch can have up to 1.5 deg. offset
  - Instrument Cable Compliance
    - Coupling matrix assumes perfectly stiff instrument cables, which certainly are not
    - Dominant source of hooping error

- A typical symptom: joint hysteresis.
  - Encoder (blue) measures accurate tracking.
  - Magnetic tracker (red) says otherwise.
- A simple cable stretch model can explain this hysteresis…

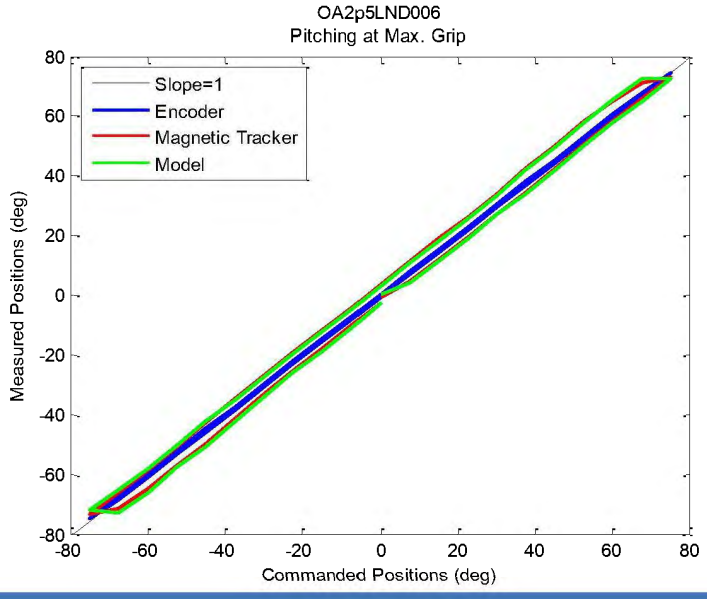




$$\Delta\theta = \frac{\Delta x}{R} = \frac{T \cdot C}{R} = M \cdot C$$

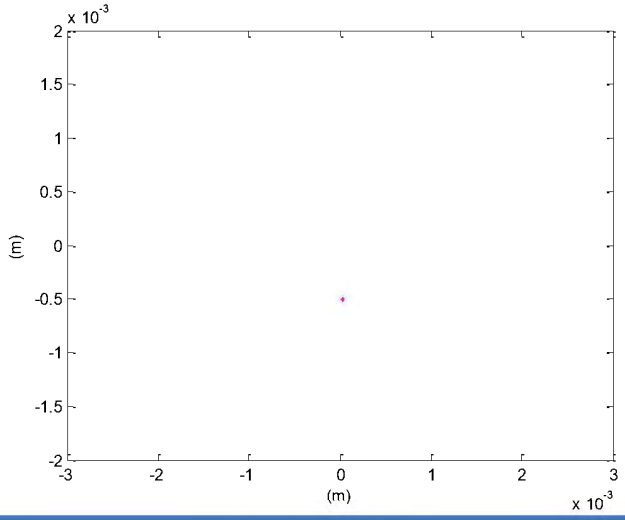
- $\Delta\theta$ is the disc motion that does NOT contribute to any tool motion.
- Think of an effective disc position that lags the actual position by $\Delta\theta$

- Model estimate the “true” joint position accounting for cable compliance.
- Works very well to explain the hysteresis in both wrist pitch and yaw.

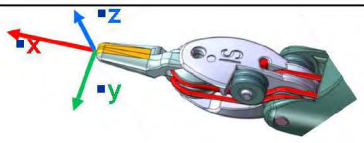


Hooping Error

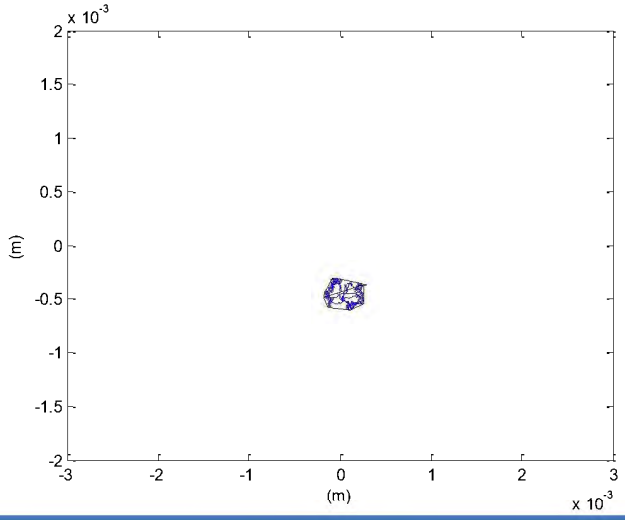
- Run joint angle trajectories through forward kinematics to "simulate" hooping performance.
- With commanded joint trajectories.
  - Max. Interior Distance: 0.032 mm



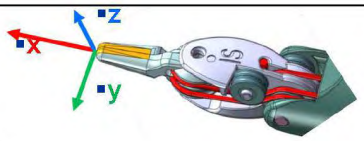
Hooping Error



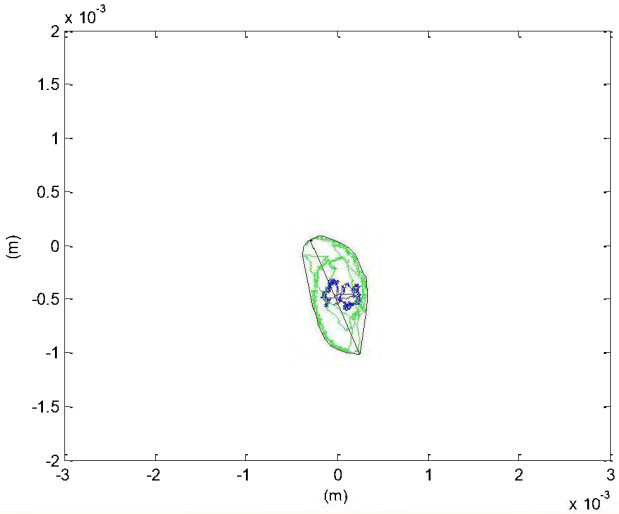
- With measured joint trajectories.
  - Max. Interior Distance: 0.454 mm



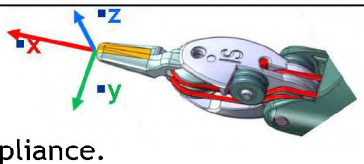
Hooping Error



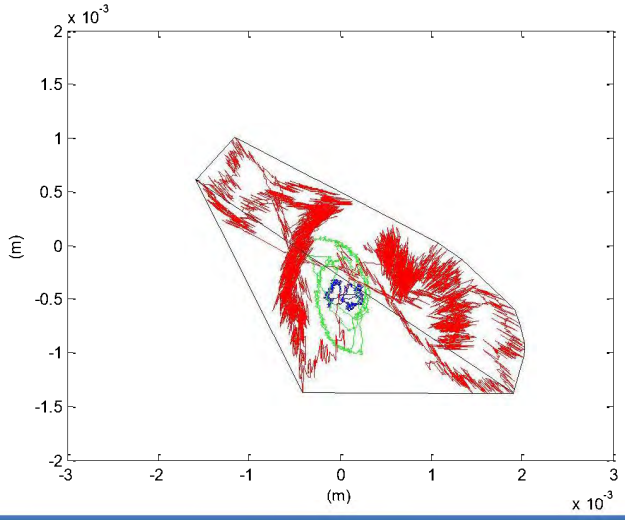
- With measured joint trajectories + backlash model.
  - Max. Interior Distance: 1.194 mm



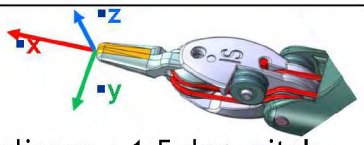
Hooping Error



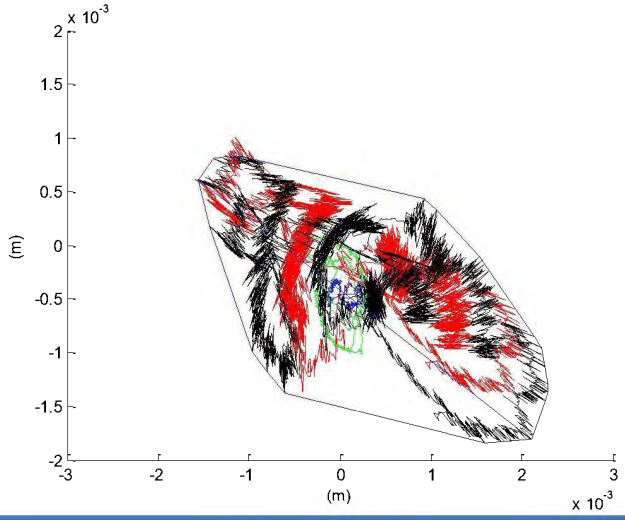
- With measured joint trajectories + backlash + compliance.
  - Max. Interior Distance: 4.02 mm



Hooping Error

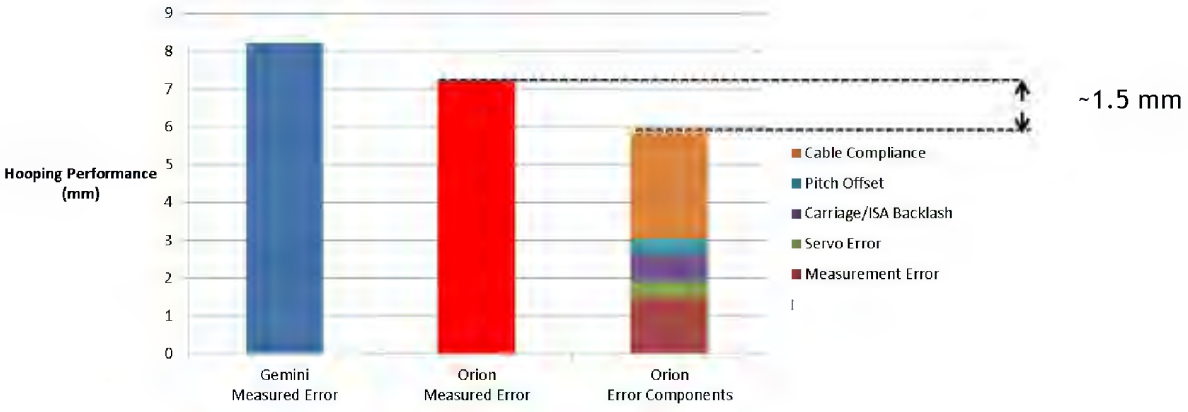


- With measured joint trajectories + backlash + compliance + 1.5 deg. pitch offset.
  - Max. Interior Distance: 4.385 mm



Hooping Summary

- A typical Orion and Gemini LND at life10:



- Orion hooping performance is comparable to IS3K for LNDs.
- Roughly 1.5 mm un-modeled error remains.

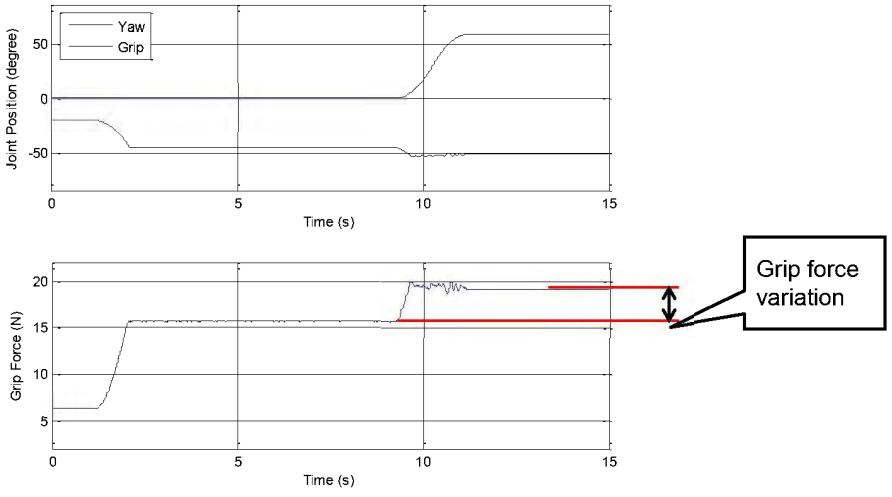
3 bar chart

Grip Force Variation

- Want to maintain a constant grip force.
- Grip force measured by a load cell along with a high-bandwidth amplifier.
- Maneuver:
  - Full grip → yaw to a fixed position → stop.

Typical Grip Variation Graphs

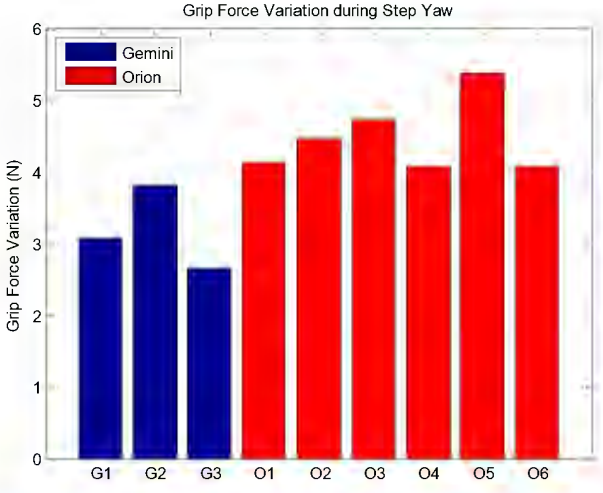
- Look at the difference between initial and ultimate grip force.



- Model shows (backup slides) grip variation is equal to the drivetrain friction

Orion vs. IS3000

- 3 new Gemini "blue" LNDs and 6 new Orion A2.0 LNDs.
  - On average, the grip force variation is 40% higher on Orion.
  - Alpha3 carriage friction reduction will reduce the variation.



Grip Variation Summary

- Observe higher grip variation on Orion LNDs.
- Grip variation is exactly the static drivetrain friction during initial grip.
- Consistent with the higher friction measured on Orion.
- Should improve with lower friction Alpha3 design. Dramatic lower friction in the A3.0 motor/gear box.

Instrument Reliability and Safety

- Reliability
  - Simulated life testing
  - Sine cycling to failure
- Safety
  - Back driving the instrument wrist against holding motor torque

Instrument Reliability, Test Design

- All tests on Production Gemini Instruments and Alpha 2.5 Orion Instruments
- Simulated Life Testing Design(for Large Needle Driver only)
  - Automated Simulated Lives (10 Lives)
  - Includes ultrasonic wash, lube and autoclave for each life.
  - Performance Testing during life span
    - Initial performance (life 0)
    - After first wash/autoclave performance (life 0.5)
    - Then after 1, 5, and 10 lives

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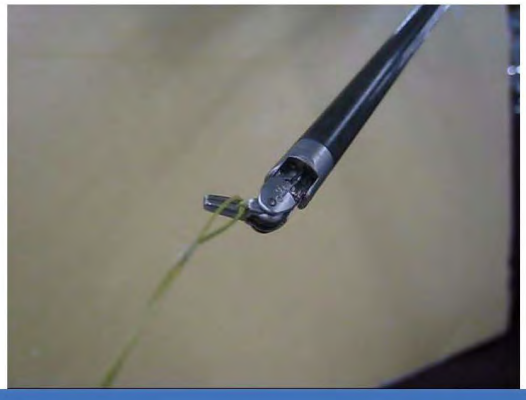
Instrument Reliability, Test Design

- Life Testing Design(for Large Needle Driver only)
  - Simulated Lives
    - 1 Life = From Life Test Protocol for Mega Needle Driver
      - 150 Suture Pulls (more to compensate for no "Tissue Lifts")

INTUITIVE SURGICAL®

Instrument Reliability, Test Design

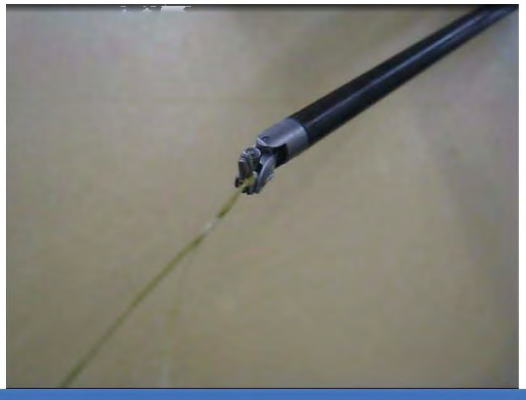
- Life Testing Design(for Large Needle Driver only)
  - Simulated Lives
    - 1 Life = From Life Test Protocol for Mega Needle Driver
      - 150 Suture Pulls (more to compensate for no "Tissue Lifts")
      - 30 Needle Throws + Pull Throughs



INTUITIVE SURGICAL®

Instrument Reliability, Test Design

- Life Testing Design(for Large Needle Driver only)
  - Simulated Lives
    - 1 Life = From Life Test Protocol for Mega Needle Driver
      - 150 Suture Pulls (more to compensate for no "Tissue Lifts")
      - 30 Needle Throws + Pull Throughs
      - 120 Wrist Circles
      - Differences: Instrument changes not performed, No Dips in Pig Blood.



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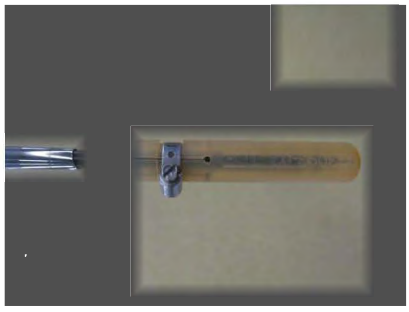
Instrument Reliability, Test Design

- Life Testing Design(for Large Needle Driver only)
  - Performance Testing during life span
    - Ascension Tracking Measurements
      - Hooping Performance
      - Joint hysteresis
    - Disc Offset Measurement
    - Friction Measurements



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Instrument Reliability, Test Results

- Life Testing Results(for Large Needle Driver only)
  - 6 Orion LND's tested
    - Wrist Pitch Cables Tensioned to 7 lb (vs. 5 lb on Gemini LND)
    - Wrist Yaw Cables Tensioned to 3 lb (vs. 5 lb on Gemini LND)
  - 3 Production LND's tested
  - Failures/Breakages:
    - No Instrument Failures during 10 simulated life test.

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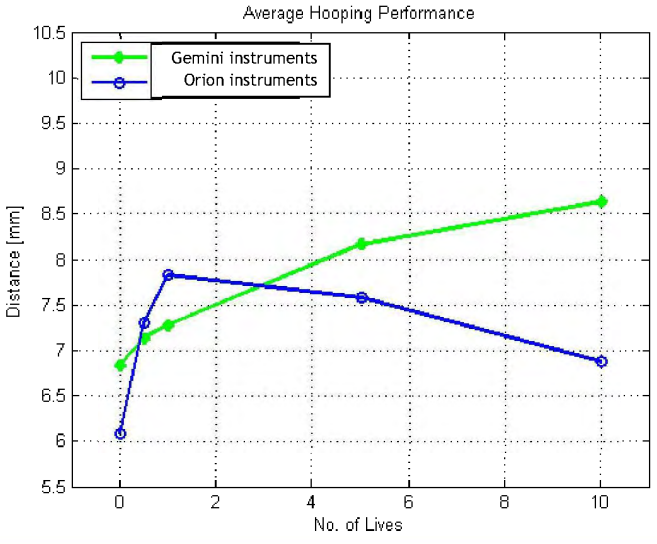
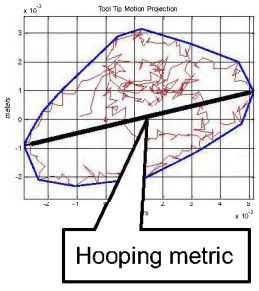
Instrument Reliability, Test Results

- Ascension Tracking Measurements: Hooping Performance
  - Orion on par with Production Gemini

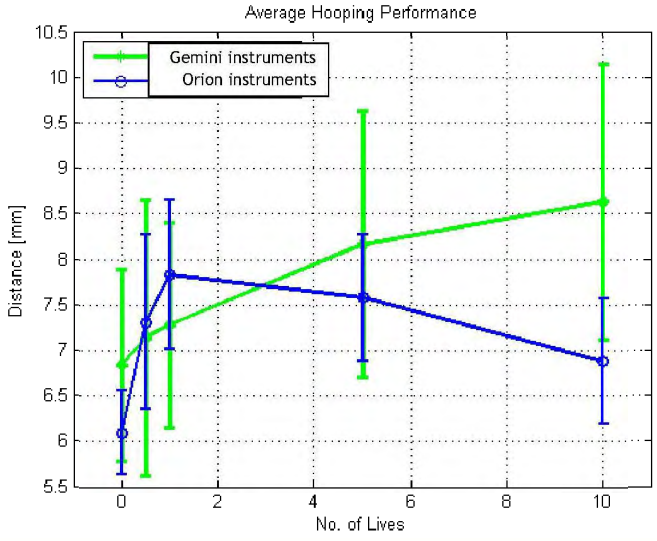




should stress again that the hooping is good on orion

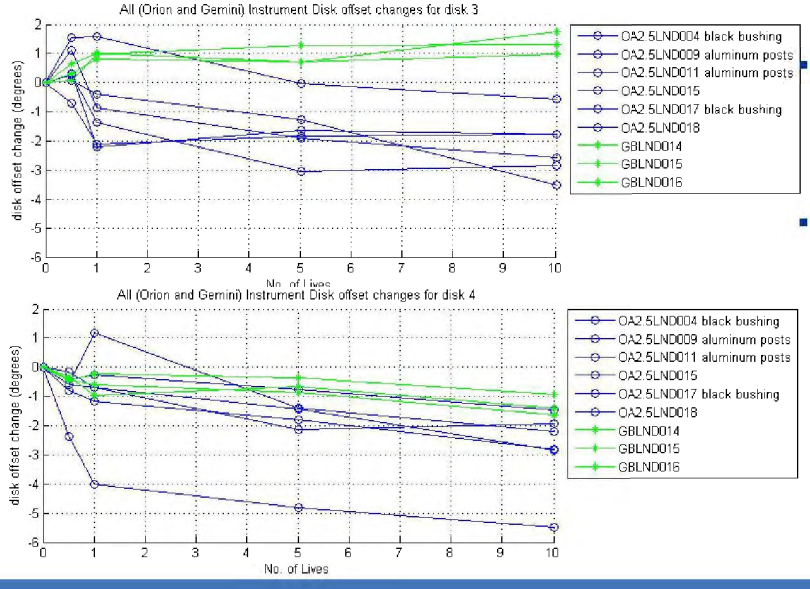
Instrument Reliability, Test Results

- Ascension Tracking Measurements: Hooping Performance
  - Orion on par with Production Gemini with less variability



Instrument Reliability, Test Results

- Disk Offset Changes: Group Comparison, Disks 3 and 4 (yaw/grip)
  - Consistently more movement on Orion Disk offsets. (w/ one outlier)



- Grip Cal Compensation should result in no detrimental performance effects.
- Hooping not affected due to symmetry of drift.

Instrument Reliability, Test Design

- Grip Max and Sine Cycle Yaw until distal cable breakage
  - To test common failure mode at distal idler pulleys.

Instrument Reliability, Test Results

- Grip Max and Sine Cycle Yaw (discrete cosine trajectory start/stop, check) until distal cable breakage

Gemini Failures	Orion Failures
641 cycles	660 cycles
605 cycles	457 cycles
579 cycles	436 cycles

Note: The grip torque at the motor for Orion instrument was at 0.18 Nm compared to 0.16 Nm for IS3000. However, the grip force generated was comparable.

Instrument Reliability, Results

- Why do the Orion Instruments break sooner in Max Grip Sine Cycle?
  - Orion Stiffer Drive Train May cause higher wrist yaw peak torques?
  - Gemini back end friction increase during test "protecting" wrist?
  - RISK: Priority for further investigation.
    - Measure grip with grip meter during test.
    - Determine fastest acceleration on WY in following
    - Match Sine or Cos Trajectory to be within reasonable acceleration bounds
    - Tune maximum grip torque on Orion to better match IS3000 grip forces.
    - Sensitivity study (to max grip torque).

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Instrument Safety, Back driving Pitch and Yaw

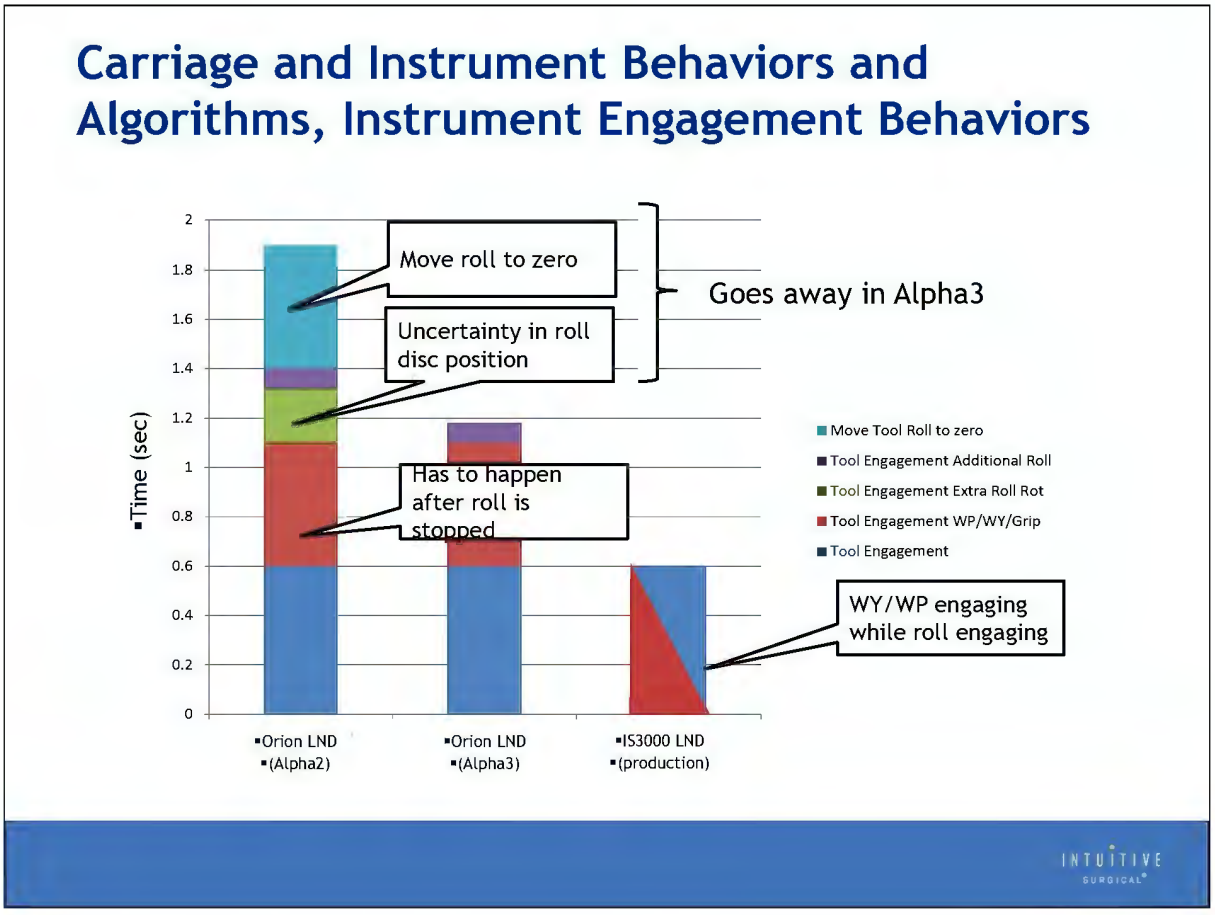
	Pitch back driving result	Yaw back driving result
IS3000	Reached ROM limit but did not break against holding torque of 0.4 Nm at the motor.	Yaw cable broke at the wrist beyond 0.35 Nm motor holding torque (tested in increments of 0.05 Nm holding torque at the motor)
Orion	Reached ROM limit but did not break against holding torque of 0.45 Nm at the motor.	Yaw cable broke at the wrist beyond 0.35 Nm motor holding torque

Result of back driving the pitch

Result of back driving the yaw

Instrument Behaviors and Algorithms

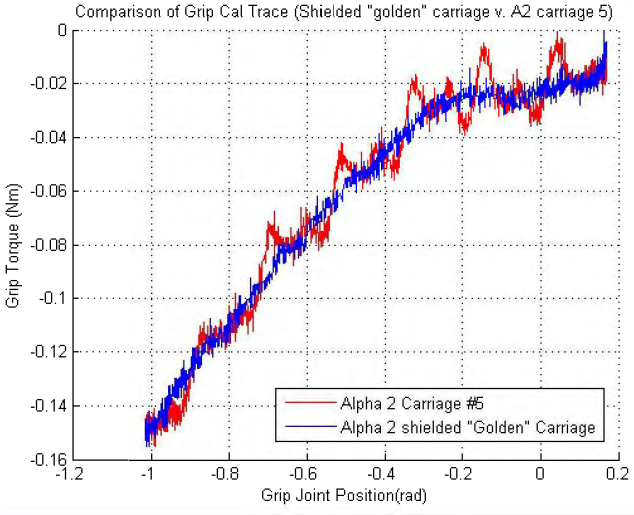
- Instrument engagement behaviors
- Grip Cal
- Cone Limits
- Instrument Data, Disc Offsets, Plug-N-Play



Arbitrary disk offsets on instruments: unable to ensure that we start "on one side" of engagement.
wrist pitch, wrist yaw and grip engage only when roll is stopped or moving slowly (cannula scraping). (+0.5 sec)
roll, an additional full rotation on roll(+ 0.25 sec), followed by second behavior to go to zero roll (+0.5 sec) (Eliminated by fixed roll disk offset)
120 deg greater ROM on roll. (+0.08 sec)

Carriage and Instrument Behaviors and Algorithms, Grip Cal

- Finds the grip close position
- "Torque Ripple" in Alpha 2 Carriages prevented accurate determination of tool bumper. Tuning deferred to Alpha 3.



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Carriage and Instrument Behaviors and Algorithms, Wrist Cone Limits

- To ensure intuitive virtual slave limit feedback to masters, Wrist Cone Limits are now turned on for all Orion Instruments (IS3000 only snake wristed, LND & BD Micro)
  - Results in reduction in wrist range of motion (inside the joint limits, especially when close to the remote center)
  - Example: Monopolar Spatula instrument
    - Joint signal ranges: WP: 80 deg, WY: 85 deg.
    - At 0.25m insertion, Wrist Cone Limit = ~78 degrees
    - At 0.035m insertion, Wrist Cone Limit = ~65 degrees.
      - Loss of 20 deg of WY motion = loss of ~6mm of reach back
  - Algorithmic fix needed.
    - IS3000 does work well.

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Carriage and Instrument Behaviors and Algorithms, Instrument Data/RFID Tags

- Header Data (programmed into RFID and tested to work)
  - Tool UID
  - Laser ID/Tool SN (used for energy mapping)
  - Disc Offsets
- Plug-N-Play Data (not yet programmed and tested)
  - Plenty of memory space on the RFID tags.
  - Not believed to be a risk

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Orion Instrument RFID Tags

Testing Summary

- Two different RFID tag companies are developing a RFID tag for ISI
- The next round of autoclave testing will be done in the CT Office and will include cleaning and sterilization cycles that are done in a Pre-Vacuum autoclave and that are not batched
  - This testing will be the most similar to what conditions the parts will see in the field
  - Testing with a read/write every 5 cycles at a nominal read distance
- Each company can provide us with a tag(s) that can fulfill different requirements for Orion

Company	Protocol: ISO 15693	Protocol: ISO 14443-B	Preferred Atmel Chip	Autoclaveable	Gamma Stable	Application: Instrument vs. Cannula
RCD Technology		X	X	X		Instrument
NewAge Industries	X			X	X	Both
NewAge Industries		X	X	X		Instrument

- Future Testing Plan:
  - 1000 samples received from RCD and are ready to start testing around 10/3/11
  - 1000 samples due from NewAge (ISO 15693) on 11/11/11
  - 1000 samples from NewAge (ISO 14443-B) with preferred Atmel chip is still TBD because of issues for NewAge sourcing chip from Atmel

IS4000 8mm Base Instruments CDR

Verification and Validation Outline

819005-03 Rev A

Top Level Test Plan

REQUIRED V/V TESTING FOR IS4000 INSTRUMENTS:

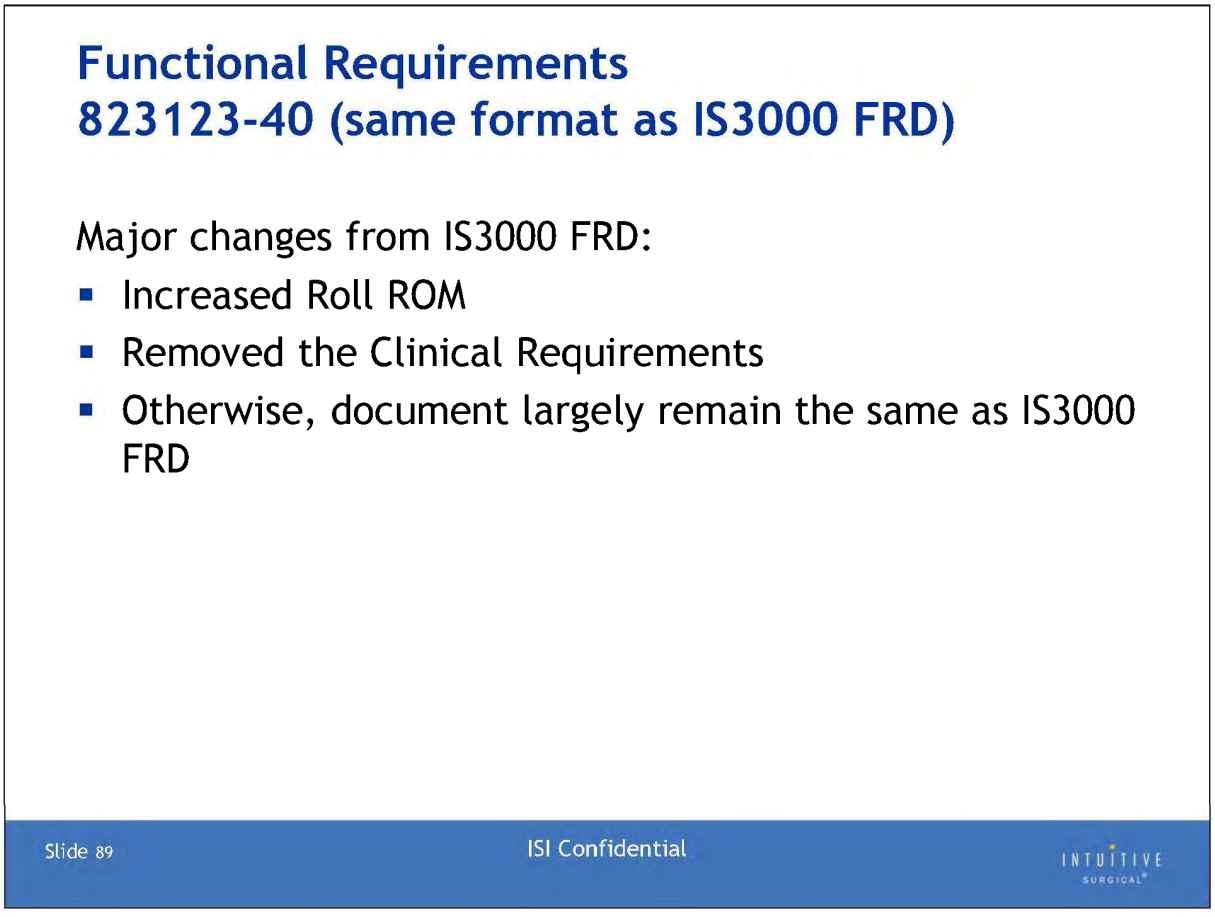
- **Design Verification** - *One Protocol covering general instrument architecture plus individual protocols for each instrument.*
- **Design/Clinical Validation** - *One Protocol covering general instrument architecture plus individual protocols for each instrument.*
- **Software Compatibility/Validation**
- **Reliability/Life Testing** - *Separated into 6 protocols, based on intended function of the instrument. (1) Monopolar Instruments, (2) Bipolar Instruments, (3) Needle Driver Instruments,(4) Grasper Instruments, (5) Clip Applier Instruments, and (6) Specialty Instruments*
- **Electrical Safety and EMC Testing**
- **Cleaning Validation**
- **Sterilization Validation**
- **Biocompatibility** - *No new materials at this time.*
- **Surgeon Evaluation**
- **Packaging Validation** - *Longer instrument will require new box*
- **Human Factors**

Architectural Requirements 823033-40 (same format as IS3000 ARD)

Major changes from IS3000 ARD:

- Update Reference section
- Instrument over-all dimensional changes:
  - Width of backend narrower
  - Height of backend larger
  - Length 2" functionally longer past remote center (except for Harmonic Ace)
  - New foot print for Instrument-to-ISA disks
- Adding fifth input
- Requirements for RFID function added
- Established new "datum" to measure length of instrument
  - Was from centerline of distal input disks to distal tip of instrument
  - Now is from bottom of chassis to distal tip of instrument
- Use 5th axis as a end of life indicator

Update! Craig Tsuji


Functional Requirements
823123-40 (same format as IS3000 FRD)
Major changes from IS3000 FRD:
Increased Roll ROM
Removed the Clinical Requirements
Otherwise, document largely remain the same as IS3000 FRD
Slide 89
ISI Confidential
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Scott H.

IS4000 8mm Base Instruments CDR

Manufacturing Overview

819005-03 Rev A

Part Numbers

- Planning BOM PB-OR-A3-INST
  - Distal Assemblies (same as current instruments)
  - 18 instruments
- Planning BOM PB-INST-A3NEW
  - Proximal Assembly (common parts)
  - 19 parts
- Assy BOM
  - 7 Instruments at -01X

Number	Description
470006-01X	ASSY,LARGE NEEDLE DRIVER,8MM,IS4000,ENG
470033-01X	ASSY,BLACK DIAMOND MICRO FORCEPS,8MM,IS4000,ENG
470172-01X	ASSY,MARYLAND BIPOLAR FORCEPS,8MM,IS4000,ENG
470179-01X	ASSY,MONOPOLAR CURVED SCISSORS,8MM,IS4000,ENG
470183-01X	ASSY,PERMANENT CAUTERY HOOK,8MM,IS4000,ENG
470189-01X	ASSY,DOUBLE FENESTRATED,8MM,IS4000,ENG
470205-01X	ASSY,FENESTRATED BIPOLAR FORCEPS,8MM,IS4000,ENG

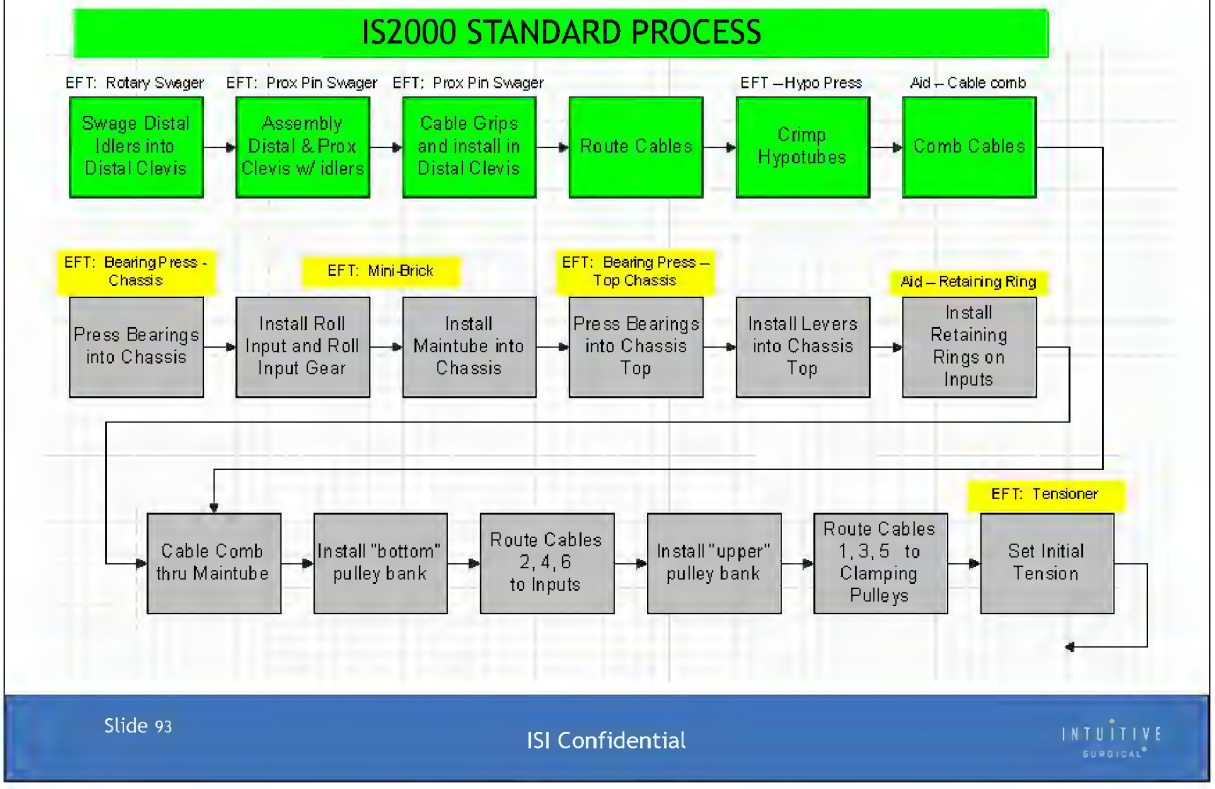
Manufacturing Strategy

Instrument Front-end VS Instrument Backend

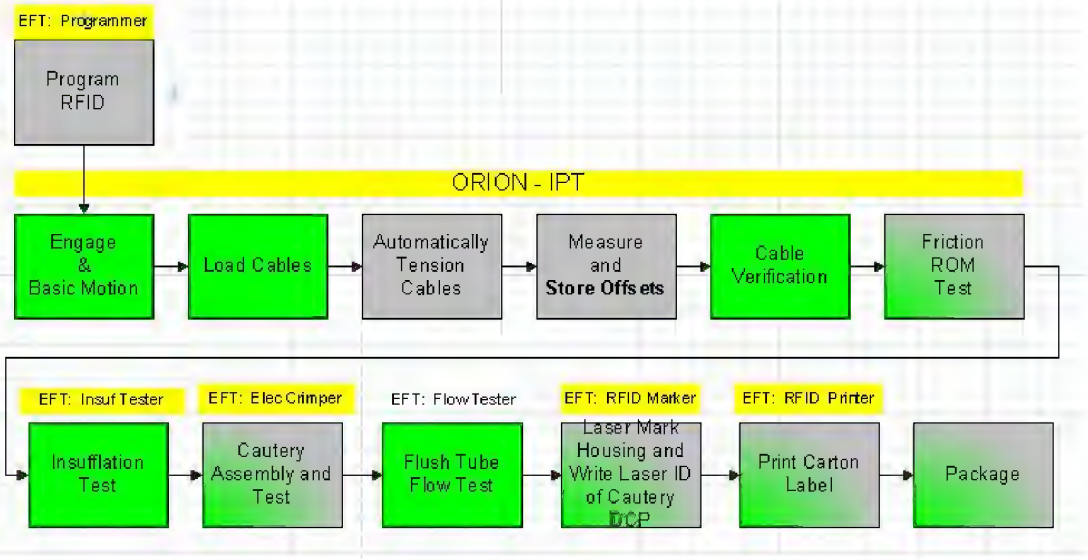
- Leverage current processes where available at front-end:
  - Common grips IS2000 provide volume & cost benefits.
    - Production methods benefit from known, mature processes.
  - Similarities to IS2000 reduce risks at launch.
- Focus on changes at Backend
  - DFM advantages over IS2000
    - No handcrimping of cables, auto tensioning, no re-tensioning required
  - Requires development of new assembly fixtures.
  - RFID requires new "DCP" like programming solution.
  - IPT Tester - new fixture to support 5 axis and process improvements.

Luis S and Greg R

Process Development / Assembly Tooling

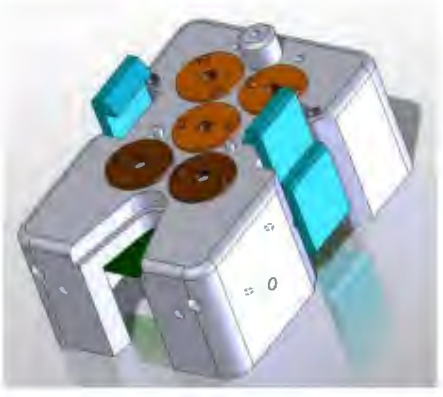


Process Development / Test Process



Tooling Requirements

- Assembly Tooling
  - **Cable Combs** – Same at IS2000 but longer
  - **MINI-Brick** –
    - Hold / Position Instrument
    - Restrain Input rotation
  - **Bearing presses – install bearings**
  - **Tensioner – set initial Tension**
  - **Snap ring tool**



Tooling Requirements - cont

- **RFID Programmer**
  - New HW / SW System
  - Hardware to interface to instrument / RFID
  - SW to support required functionality
  - Functionality of current "DCP" -
    - Program and verify instruments
    - Read instrument information for IPT, Marker, and Labeling system.
    - Write and verify process control flags.
    - Maintain security of programming system
  - NEW - Write instrument OFFSETs to RFID Chip
  - NEW - Read Energy Dallas ID and write to RFID Chip

- Resources
  - ME - Mechanical layout
  - TE - HW
  - TE - Diagnostics (SW)

Orion IPT

- New HW / SW System
- 5- Axis drive capability
- Functionality of current IS1200/2000 IPT -
  - Read instrument and load test scripts
  - Offset Measurement
  - Range of Motion/Friction
  - Cabling Verification
- NEW - Write OFFSETs to RFID Chip or DCP
- NEW - Automatic Cable Tensioning
  - Consistent cable tensioning
  - Allows use of advanced techniques
- Next Phase is S/W integration by mid/late Oct

- Resources
  - ME - Mechanical layout
  - TE - HW / Controls
  - Test Eng Diagnostics (SW)

Production Line Lifecycle Development

Alpha
- Alpha 3 (Q4) - IPT and DCP offline - develop Orion specific line
- Alpha 4 (Q1) - IPT and DCP online - initiate EFT qualification

Beta
- Complete final EFT qual
- Perform process validation

Gamma
- Duplicate Orion line(s) in support of launch volumes
- Launch builds in Sunnyvale

Production
- Demonstrate stability
- Transfer to Mexicali plant -

Supply Base

- Prime components follow current IS2000/3000
  - Cables / Hypotubes – Baird Industries
  - Grips / Clevis – Britt / Indo-MIM / Remmele
  - Maintubes – Easton
  - Injection Molding – UPG

- New Parts/Suppliers
  - Hypotubes - New process at Baird
  - RFID - New process at RCD and New Age Industries
  - Clamping Pulley - Swiss Precision

Process Validation Plans

- Process Validation to follow standard instrument format
  - Demonstrate EFT functionality and PMC
  - Demonstrate availability of work instructions and trained technicians.
  - Execute three build lots (10 units minimum) for each instrument type.
  - Evaluate In-process Testing results.
    - Gather Variable Data and Assess margin to spec
  - Evaluate product quality against specification. (PQA functional test)
  - Evaluate Labeling and DHR documentation.

Material Costs

MATERIAL COST

	IS2000	IS4000	Com
LND	$ 157	$ 151	$ 89
Bipolar	$ 181	$ 180	$ 128
MCS*	$ 270	$ 269	$ 135

* MCS includes cost of 1 Tip Cover

- Instrument COGS is driven by Grip and Cable costs.
- Hypotube cost estimate may increase due to process limitations
- IS4000 cost reduction is sensitive to cost of bearings.
- Moderate improvement to standard Labor & O/H by DFM.
- Stored Offsets to have significant impact on Mfg efficiency (first pass yield)

IS4000 8mm Base Instruments CDR

Current RMA Trends

819005-03 Rev A

Predecessor Instrument RMA

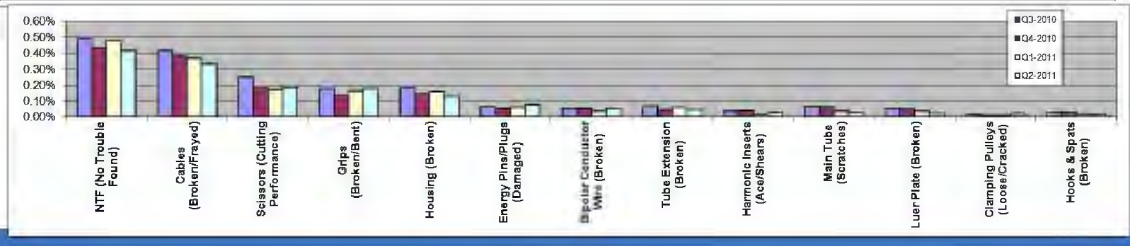
Instrument FA
(Normalized by Procedure)

>.0% | >.10% | >.20% | >.30% | >.40% | >.50%

Complaint: YES

Failure Analysis	Q3-2010 Proc. 69,618 QTY	Q3-2010 %	Q4-2010 Proc. 78,096 QTY	Q4-2010 %	Q1-2011 Proc. 81,395 QTY	Q1-2011 %	Q2-2011 Proc. 88,436 QTY	Q2-2011 %	Trend	Notes	Action Tracking	Owner
TOTAL	1398	2.01%	1301	1.67%	1343	1.65%	1402	1.59%	—			
NTF (No Trouble Found)	341	0.49%	339	0.43%	390	0.48%	367	0.41%	↓	IPT under development for iRMA team	N/A	GirishS
Cables (Broken/Frayed)	289	0.42%	296	0.38%	299	0.37%	293	0.33%	↓			
Scissors (Cutting Performance)	172	0.25%	138	0.18%	134	0.16%	162	0.18%	—			
Grips (Broken/Bent)	121	0.17%	102	0.13%	133	0.16%	153	0.17%	—			
Housing (Broken)	124	0.18%	112	0.14%	126	0.15%	110	0.12%	↓	Design update (materials) implemented	C45185	SharkS
Energy Pins/Plugs (Damaged)	41	0.06%	40	0.05%	47	0.06%	64	0.07%	↑	Design update (loctite/chassis) in-progress	C52176	LewisI
Bipolar Conductor Wire (Broken)	35	0.05%	41	0.05%	27	0.03%	46	0.05%	—	Supplier update (cables) under investigation	C53212	MikeB
Tube Extension (Broken)	49	0.07%	34	0.04%	45	0.06%	37	0.04%	↓	Design update (3 to 4 keys) implemented	C43819	MikeB
Harmonic Inserts (Ace/Shears)	25	0.04%	32	0.04%	14	0.02%	24	0.03%	—	Shears (Clamp Arm) Ace (Broke Blade/Self-test)		
Main Tube (Scratches)	45	0.06%	46	0.06%	29	0.04%	21	0.02%	↓			
Luer Plate (Broken)	36	0.05%	37	0.05%	28	0.03%	19	0.02%	↓	Design update (-05) implemented	C46402	SharkS
Clamping Pulleys (Loose/Cracked)	9	0.01%	8	0.01%	8	0.01%	17	0.02%	↑	Torque specification added to drawings	C52702	SharkS
Hooks & Spats (Broken)	18	0.03%	22	0.03%	15	0.02%	15	0.02%	↓	Design update (-06) implemented	CAPA1339	MikeB
Other	93	0.13%	54	0.07%	48	0.06%	74	0.08%	—			

Overall complaint rate stable (flat) - several design improvements shipping to customer base.
Harmonic inserts monitored for Shears vs Ace failure modes and rates.



Slide 103 QRB 2011 Q2 INTUITIVE SURGICAL

Orion Instrument Comparison

Historical Failures	Orion Mitigations
No Trouble Found	No specific mitigations planned
Drive Cable failure	Improved Cable tension control
Scissor cutting performance	Cut Test Validation
Grips Bent/Broken	Life Test Validation
Housing Broken	Using Radel material
Energy Plugs Damaged	New connector design minimizes the pin exposure
Conductor Wire Break	Life Test Validation
Tube extension broken	Life Test Validation
Harmonic Inserts	N/A for Orion standard instruments
Main Tube scratches	Easton Tube material
Luer Plate broken	Cleaning and Life Test Validations
Clamping Pulleys Loose/cracked	Life Test Validation
Hooks-spats (Plastic clevis)	Architectural Requirements for axial load Non-glass-filled Ultem 1000 distal clevis

Highlight the effective specs. Drive cable failure and Energy Plugs Damaged

IS4000 8mm Base Instruments CDR

Project Risks

819005-03 Rev A

Project (Technical/Schedule) Risks

Item	Mitigation/Update	Risk
Excess hooping due to compliance and/or backlash	- See Performance Slide	Low
Long instrument - increased potential for capacitive leakage and deflection	Waiting for Alpha 3 build to test this issue Use shorter length	Low
Clinical usage of Harmonic Ace (shorter compared to other IS4000 instruments)	Work with Ethicon to develop longer Harmonic Blade Insert Use shorter length	High (if we absolutely need a longer length Harmonic Blade Insert)
Increase Roll Angle: Life Impact	Need to evaluate	Medium

Project (Technical/Schedule) Risks (con't.)

Item	Mitigation/Update	Risk
Increase engagement time	Reducing engagement time to 1.2 seconds by eliminating roll disc offset	Low
Earlier Failure from sine cycling	More testing/ investigate the root cause	High
RFID	Sterilization/life testing Reliability testing Dallas chip as a backup	Medium
Hypo-tube manufacturing	Alternate designs are being considered Improve manufacturing process Use IS3000 Hypo-tube	Medium

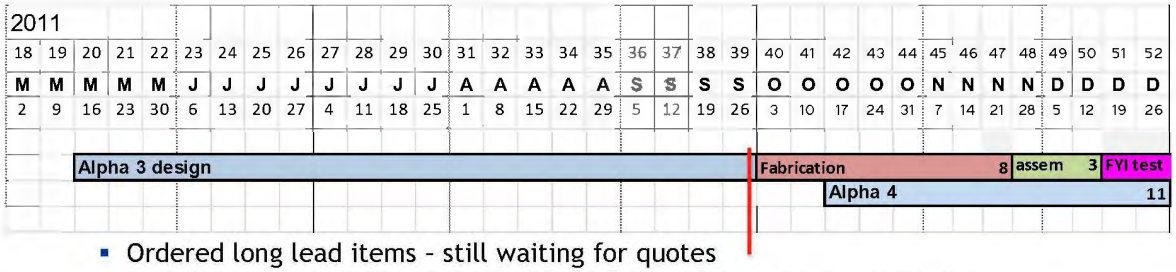
IS4000 8mm Base Instruments CDR

Project Schedule

819005-03 Rev A

ORION
FAST FOUR QUADRANT SURGERY

Orion Instrument Schedule



- Ordered long lead items - still waiting for quotes
  - Ordered machined assembly for end of October delivery (Qty: 12)
- Total ordered quantity: 500 Instruments
  - Quantity needed for testing: 231
  - Initial build quantity: Approx. 100
  - Remaining will be built per demand
- Mini Brick: due on third week of Oct.
- IPT (Phase 1): due on second week of Nov.
- Alpha 4 design will start third week of October
  - Concepts for the end of life indicator (Fifth Input)
  - Industrial Design
  - Harmonic Ace
- Technical reviews: End of November and December
- Alpha 4 design release: End of December

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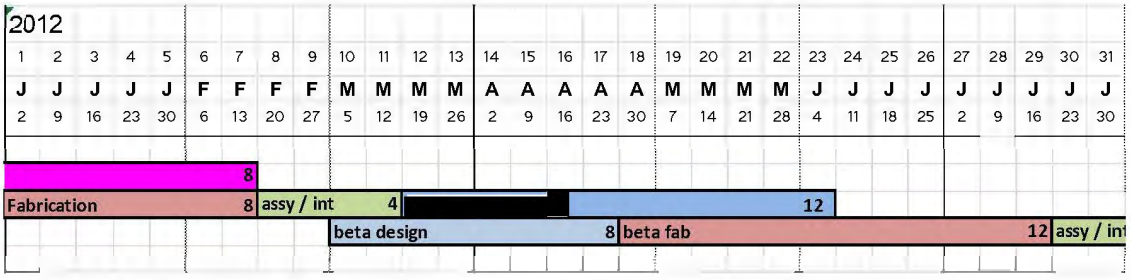
4/12/2021

Scott Harrington

Orion Instrument Schedule



- Alpha 4 fabrication: first week of January, 2012
- Finalize feasibility assessment of, fifth input (end of life indicator), and moving of the flush ports (back of the instrument).
- [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
- Finalize Beta Design: End of April, 2012
  - Technical reviews: End of March and April
- Finalize V&V strategy: End of February, 2012

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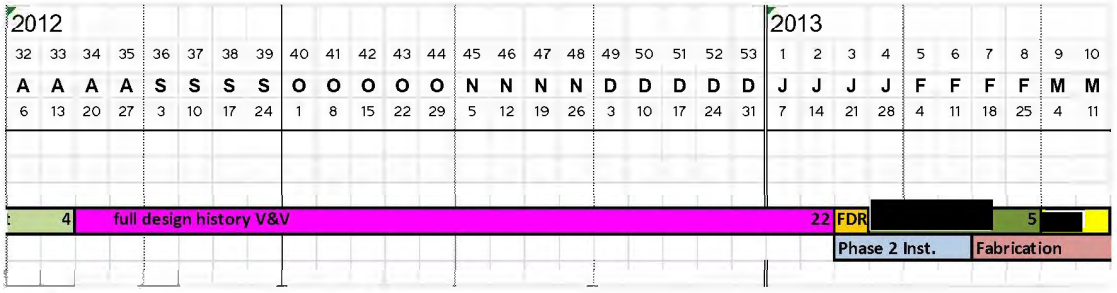
4/12/2021

Scott Harrington

Orion Instrument Schedule



- [redacted]
- FDR: Third week of January
- Phase 2 Instrument Development: Starts third week of January
- [redacted]

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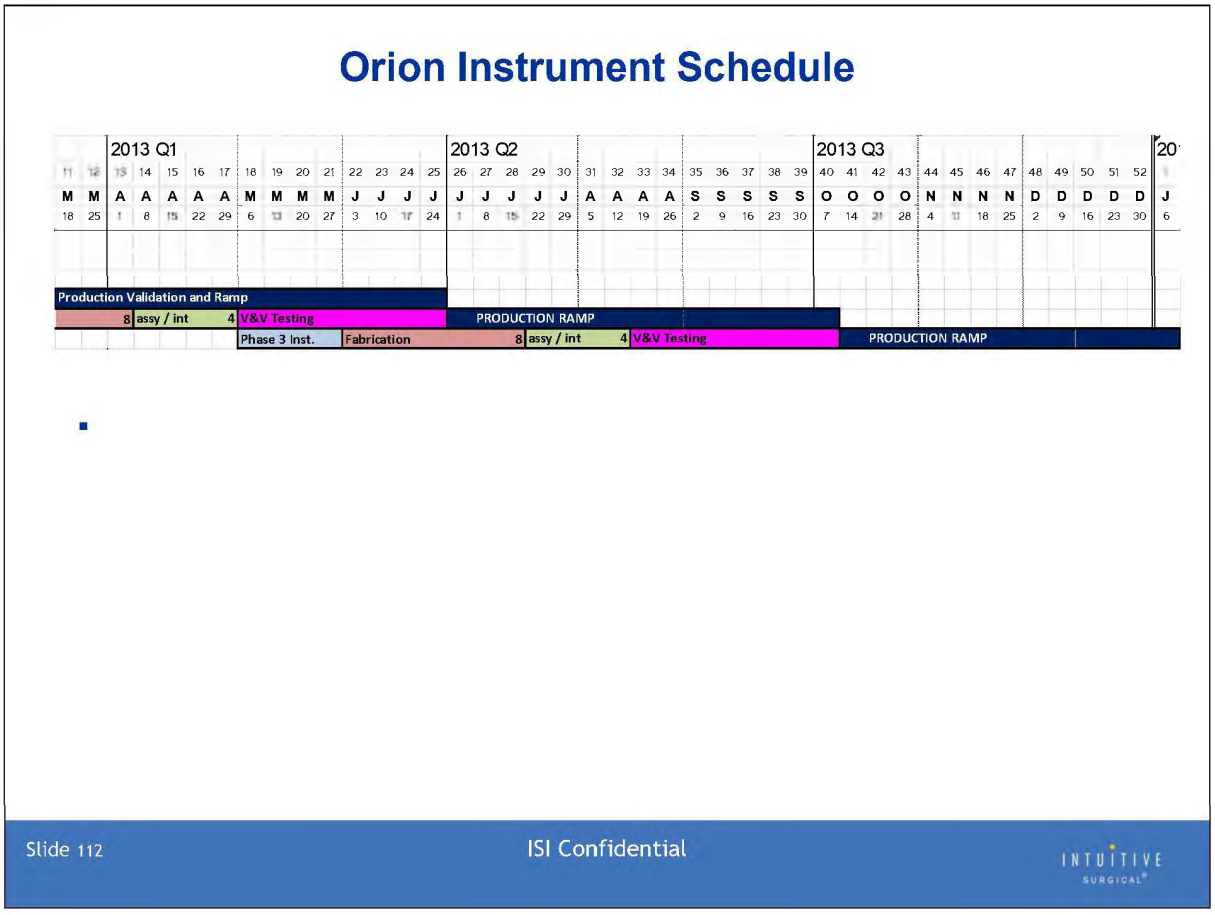


4/12/2021

Scott Harrington

Instrument Action Items from PDR – Resolved

No.	Issue/Action	Resp.	Target Completion	Final resolution	Closed
1	Evaluate optimal direction of cautery cord as it comes off the instrument housing	Greg Dachs	CDR	Cautery connector board incorporates the optimal position. CDE provided recommendation after meeting with team to review Projet prototype.	Oct, 2011
2	Add 10 – 5mm reducer to Accessory launch deliverables	Joe Orban	CDR	PDR combined Instruments and Accessories. There will be a separate CDR for Accessories and this item will be addressed at that CDR.	N/A for Instruments

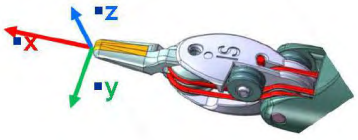
(Post-CDR Update)

Questions?

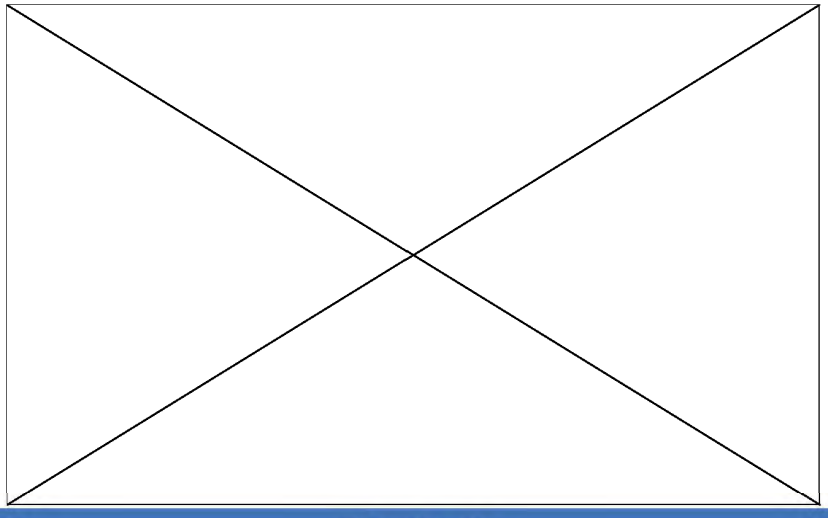
Thank You For Your Time! Please sign the attendance sheet

Backup Slides

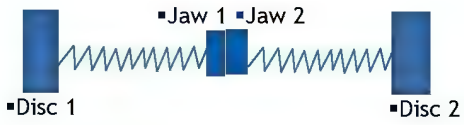
Multi-Dof Model Validation

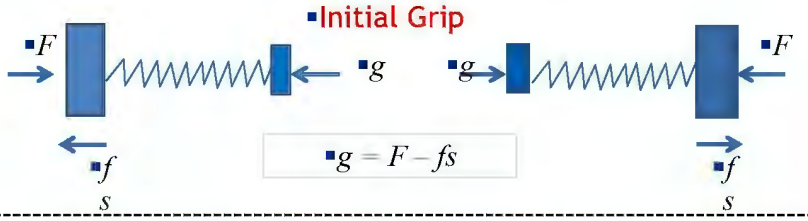


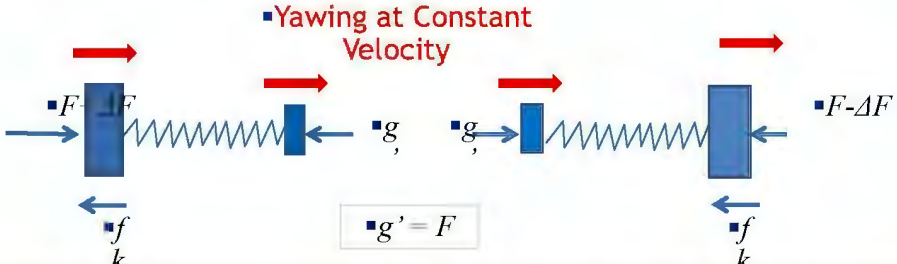
- Simultaneously exercising wrist roll, pitch and yaw.
  - Model gives estimated joint pos., which are run through forward kinematics.
  - Project tip motion on to the “y-z plane”.



- A simple mass-spring model can explain the grip variation in "grip and step yaw"







- Reducing friction helps reduce grip force variation seen in "grip and step yaw".

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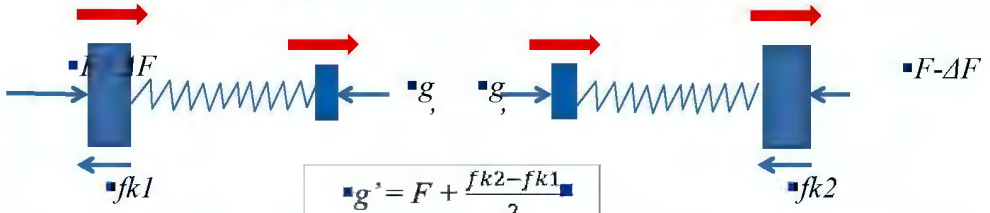
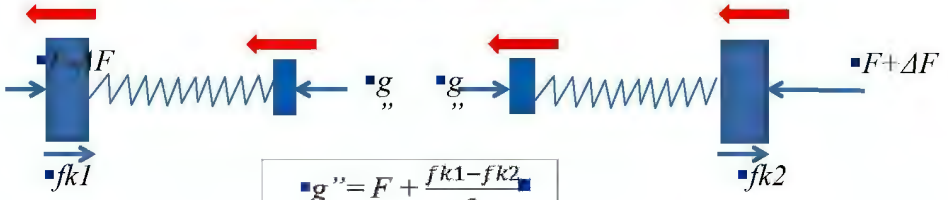
▪Yawing Right at Constant Velocity



$$g' = F + \frac{fk2 - fk1}{2}$$

▪Yawing Left at Constant Velocity

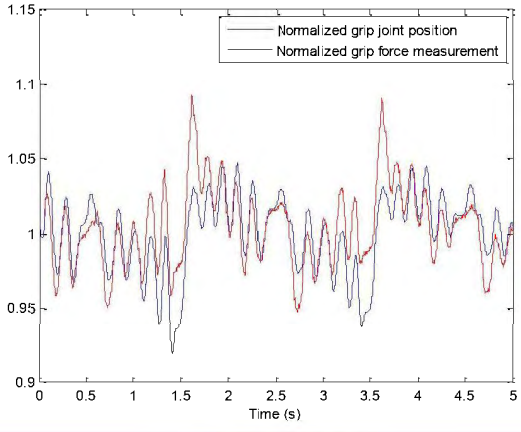


$$g'' = F + \frac{fk1 - fk2}{2}$$

$$g'' - g' = F + fk1 - fk2$$

- Equaled friction in the 2 jaws/discs helps maintain a constant grip force.

- The simple mass-spring model also says the following:
  - It is important to have balanced friction between the 2 yaw jaws.
    - Easier to achieve on Orion with disc offsets
  - It is important to maintain a constant grip torque
    - Remaining torque ripple is why Orion shows larger grip force variation during the "grip and sine yaw" move
  - "Spring" length relates to spring force
    - The grip dof position tells us a lot about the grip force variation.



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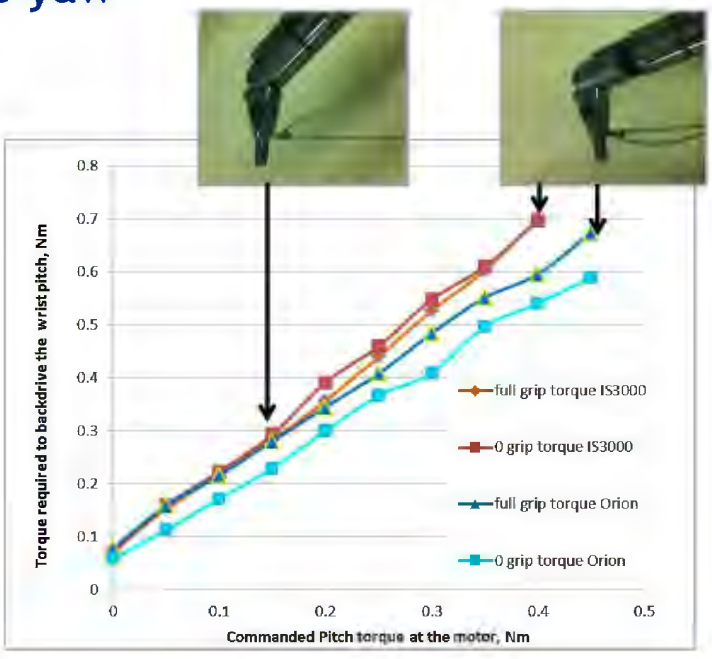
Instrument Reliability, Backdriving the pitch and the yaw



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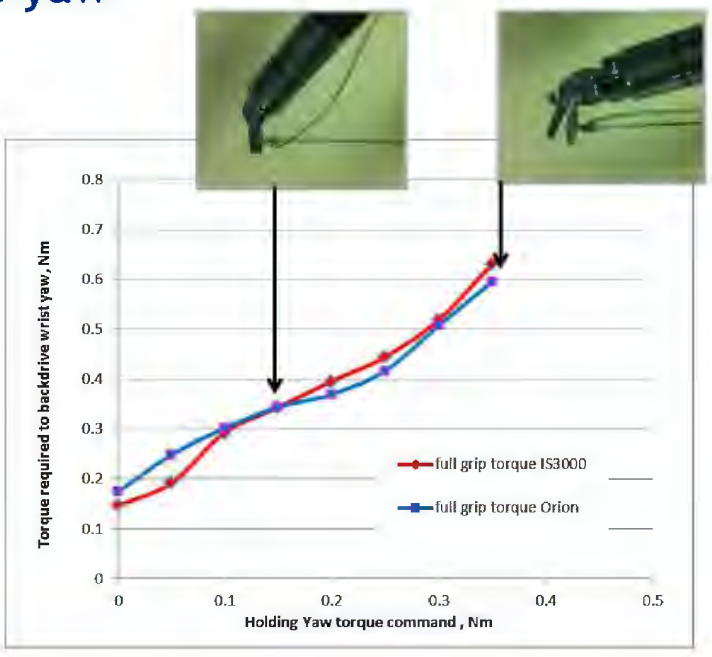
Instrument Reliability, Backdriving the pitch and the yaw



Instrument Bringup Status

- Significant additional Software/Parameter effort still required.

EndoWrist Monopolar Cautery Instruments			MDEE CREATED	PARAMETERS TUNED	SW/TUNING EFFORT
420179	*Hot Shears*™ Monopolar Curved Scissors)	Launch	YES	NO	Large
420183	Permanent Cautery Hook	Launch	YES	NO	Small
420184	Permanent Cautery Spatula	Phase 2	YES	NO	Small
EndoWrist Bipolar Cautery Instruments					
420172	Maryland Bipolar Forceps	Launch	YES	NO	Large
420227	PK® Dissecting Forceps	Launch	NO	NO	Small
420205	Fenestrated Bipolar Forceps	Launch	YES	NO	Small
420344	Curved Bipolar Dissector	Launch	NO	NO	Large
Ultrasonic Energy Intruments					
420275	*Harmonic* ACE® Curved Shears 8 mm	Launch	NO	NO	Small
EndoWrist Needle Drivers					
420006	Large Needle Driver	Launch	YES	YES	Medium
420194	*Mega*™ Needle Driver	Launch	NO	NO	Small
420309	*Mega SutureCut*™ Needle Driver	Launch	NO	NO	Medium

EndoWrist Graspers			MDEE CREATED	PARAMETERS TUNED	SW/TUNING EFFORT
420033	Black Diamond Micro Forceps	Phase 2	YES	NO	Small
420093	*ProGrasp*™ Forceps	Launch	NO	NO	Large
420049	Cadiere Forceps	Phase 2	YES	NO	Small
420207	Tenaculum Forceps	Launch	NO	NO	Small
420036	DeBakey Forceps	Launch	NO	NO	Small
420189	Double Fenestrated Grasper	Phase 2	YES	NO	Small
420xxx	Tip-up Fenestrated Grasper	Launch	NO	NO	Small
420318	*Small Graptor*™ (Grasping Retractor)	Launch	NO	NO	Medium
Clip Applier					
420230	Large *Hem-o-lok*® Clip Applier	Launch	YES	NO	Large
420327	Medium *Hem-o-lok*® Clip Applier	Launch	NO	NO	Large
Specialty Instruments					
420204	Atrial Retractor	Launch	NO	NO	Medium
420246	Atrial Retractor Short Right	Launch	NO	NO	Medium
420343	5 mm Thoracic Grasper	Launch	NO	NO	Large

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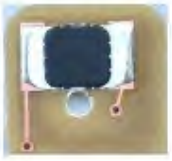
Orion Instrument RFID Tags

Testing Summary

- 6 different RFID tags from 3 different Manufacturers were tested to 301 cleaning cycles
  - 1 cleaning cycle = 15min ultrasonic cleaner, 1 autoclave cycles (no preVacuum) at 132°C for 4min (testing completed at test lab) batched into groups of 5



Tag Mfger & Type	# of test samples	Failures @ cycle #
RCD Technology † (Handmade HF 5010 Rev1 tag)	11	56, 196, 224, 245, 273, 273, 273*
Syama Tech (7mm Epoxy Autoclave)	10	140, 140, 154, 161, 182, 182, 196, 196, 196, 196
NewAge Industries † (RFID-HT-16mm High Temp Tag)	10	Zero Failures!
NewAge Industries (Part# NS1 10mm)	10	91, 161, 161, 161, 189, 280, 301
NewAge Industries (CA7991026 -7.5mm PCB Tag)	3	77, 105, 147
Atmel PN:174305	10	21, 49, 49, 49, 56, 70, 70, 84, 98

*Failure analysis showed failures were unique to chip used in prototypes

† Continued to next round of prototyping

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